Marquette

Responder® 3000

Operator's Manual

Version 2

227 490 02 GA (e) Revision C

marquette

A GE Medical Systems Company

1 Intended Use and Functional Description 5

2 Controls and Indicators 6

3 Putting the Device into Operation and Performance Check 9

4 Manual Defibrillation 18
- 4.1 Defibrillator Application Guidelines 18
- 4.2 Non-Synchronized Defibrillation 19
- 4.3 Synchronized Defibrillation (Cardioversion) 26

5 Semiautomatic Defibrillation 30

6 Pacemaker 36

7 Displaying and Monitoring the ECG 41

8 12-Lead ECG Analysis Program (12SL ™) 46

9 Pulse Oximetry (SpO_2) 49

10 Capnometry ($etCO_2$) 54

11 Memories of the Marquette Responder® 3000 58

12 Recording 61

13 Defibrillator Setup 63

14 Battery Power Operation 67

15 Test Discharge 70

16 Operation in the Vehicle Mounting Unit, Mounting the AC Power Adapter 73

17 Error and System Messages 74

18 Cleaning, Maintenance 75

19 Technical Specifications 78

20 Order Information 84

Appendix
- The Arrhythmia Detection Program 87
- EC Declaration of Conformity 88
- Index 89

Revision History

This manual is subject to the Marquette Hellige change order service. The revision code, a letter that follows the document part number, changes with every update of the manual.

P/N / Index	Date	Comment
227 490 02-A	January 1999	Initial Release
227 490 02-B	October 1999	Version 2
227 490 02-C	January 2000	ECO 064 064

General Information

- The product Marquette Responder® 3000 bears the CE marking

  CE-366

  indicating its compliance with the provisions of the Council Directive 93/42/EEC about medical devices and fulfills the essential requirements of Annex 1 of this directive.
- The product complies with the electromagnetic immunity requirements of standard IEC 60601-1-2/EN 60601-1-2 "Electromagnetic Compatibility - Medical Electrical Equipment".
- The radio-interference emitted by this device is within the limits specified in CISPR11/EN 55011, class A.
- The device is designed to comply with IEC 60601 requirements. It is a protection class I device and has an internal power source. It is classified as an MDD class IIb device.
- The CE mark covers only the accessories listed in the "Order Information" chapter .
- This manual reflects software version 2.
- This manual is an integral part of the device. It should always be kept near the device. Close observance of the information given in the manual is a prerequisite for proper device performance and correct operation and ensures patient and operator safety. **Please note that information pertinent to several chapters is given only once. Therefore, carefully read the manual once in its entirety.**
- The symbol ⚠ means: Consult accompanying documents. It indicates points which are of particular importance in the operation of the device.
- This manual is in conformity with the device specifications and standards on safety of electromedical equipment valid at the time of printing. All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.
- On request Marquette Hellige will provide a service manual.
- The Marquette Hellige quality management system complies with the standards DIN EN ISO 9001 and EN 46001.
- The safety information given in this manual is classified as follows:

Danger
indicates an imminent hazard. If not avoided, the hazard will result in death or serious injury.

Warning
indicates a hazard. If not avoided, the hazard can result in death or serious injury.

Caution
indicates a potential hazard. If not avoided, this hazard may result in minor personal injury and/or product/property damage.

- To ensure patient safety, the specified measuring accuracy, and interference-free operation, we recommend to use only original Marquette Hellige components. The user is responsible for application of accessories from other manufacturers.
- The warranty does not cover damage resulting from the use of unsuitable accessories and consumables from other manufacturers.
- Marquette Hellige is responsible for the effects on safety, reliability, and performance of the device, only if
  - assembly operations, extensions, readjustments, modifications, or repairs are carried out by Marquette Hellige or by persons authorized by Marquette Hellige,
  - the device is used in accordance with the instructions given in this operator's manual.

© Marquette Hellige GmbH 2000
Postfach 600265
79032 Freiburg, Germany
Telephone +49 761 45 43-0

1 Intended Use and Functional Description

The Marquette Responder® 3000 is a lightweight, portable defibrillator with ECG monitor and integrated recorder.

It is perfectly geared both to hospital and to prehospital use; in conjunction with the vehicle mounting unit, it can also be used in an ambulance.

There are two versions of the Marquette Responder® 3000:

– a version for manual defibrillation,
– a version for semiautomatic defibrillation which can be switched to manual operation.

Both versions are capable of delivering synchronized and non-synchronized defibrillation shocks.

The following paddle types can be used with the defibrillator: hard paddles (with integrated contact surfaces for children), adhesive electrodes and internal spoons.

The device features can be upgraded with the following options:

– a program for ECG measurement and interpretation (12SL),
– an $etCO_2$ measurement system (capnometry),
– an SpO_2 measurement system (pulse oximetry),
– a transcutaneous pacemaker.

Figure 1-1. Marquette Responder® 3000

The color concept for the displayed information lets you see at a glance whether

– the parameter reading is within the alarm limits (green),
– a technical fault is reported (blue),
– an alarm is reported (red),
– the system displays a message (yellow).

The defibrillator has the following memories for storage and documentation of the relevant procedure data:

– an event memory,
– an ECG memory,
– a trend memory, and
– a memory for the 12SL analysis results.

The integrated 3-channel recorder can be started manually and automatically.

The defibrillator is powered from

– an optional AC power adapter which is permanently attached to the defibrillator, or
– 1 or 2 plug-in batteries, or
– the vehicle mounting unit / wall mount unit.

Batteries are recharged via:

– the optional AC power adapter
– the optional charging unit, or
– the optional vehicle mounting system.

Biocompatibility

The parts of the product described in this operator manual, including all accessories, that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards. If you have questions in this matter, please contact Marquette Hellige GmbH or its representatives.

2 Controls and Indicators

The Device

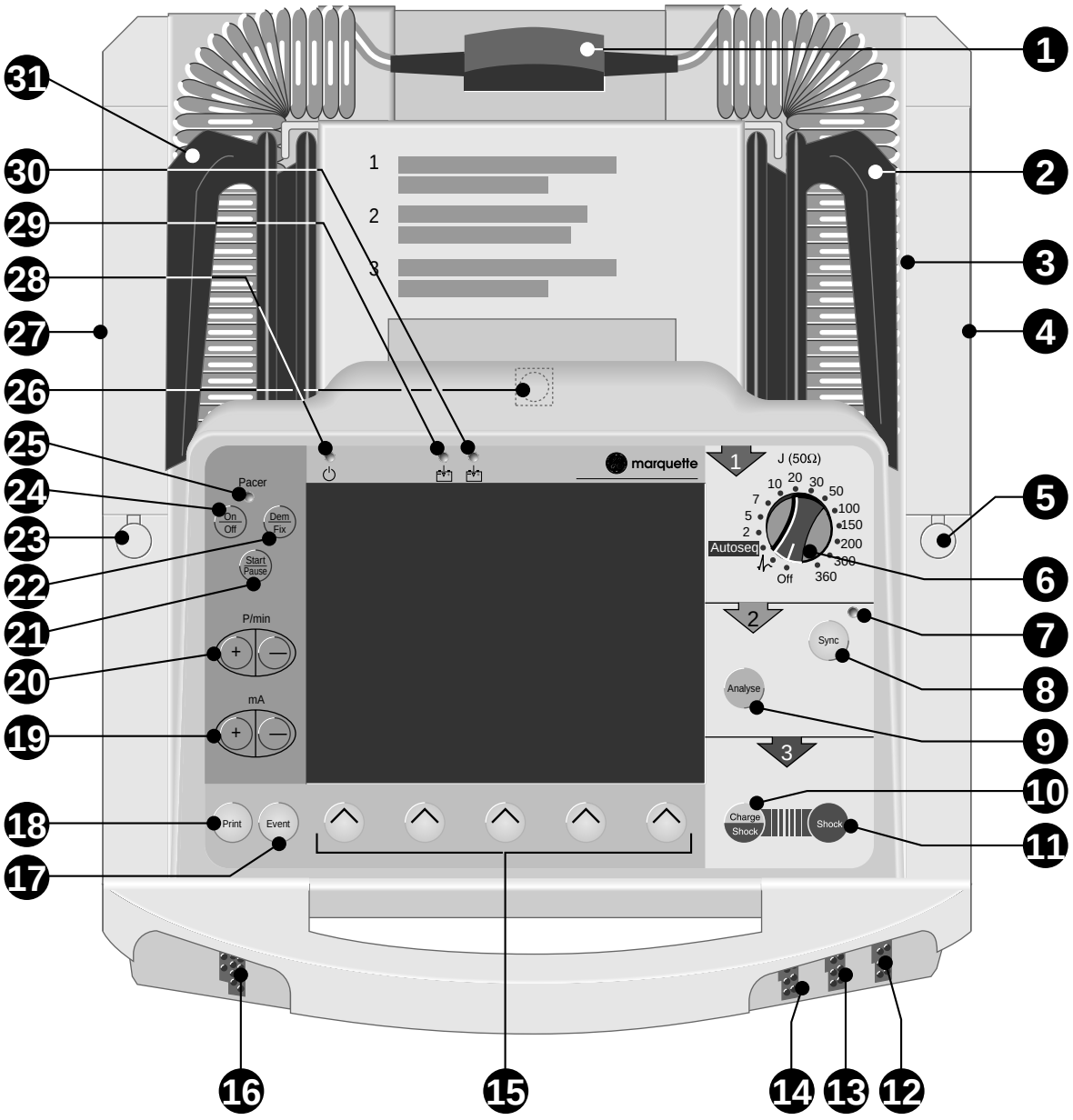


Figure 2-1. Controls and indicators of the Marquette Responder® 3000

1 *Connector for exchange of the defibrillation electrodes (switch off the device before exchanging the electrodes!)*

2 *APEX paddle*

3 *Infrared interface*

4 *Battery with "Test" button and charge level indication*

5 *Button to unlock right battery for removal*

6 *Energy selector, ON/OFF switch*

7 *Indicator, yellow, flashes to the QRS rhythm in synchronized mode*

8 *Button to enable and disable the synchronized mode (cardioversion)*

9 *Button to initiate ECG analysis in the semiautomatic mode (only on semiautomatic defibrillator models)*

10 *Button to initiate defibrillator charging and to trigger the shock (together with button **11**) when adhesive pads or internal spoons are used*

11 *Button to trigger the defibrillation shock (together with button **10**) when adhesive pads or internal spoons are used*

12 *1-Volt ECG output*

13 *$etCO_2$ signal input (optional)*

14 *SpO_2 signal input (optional)*

15 *Function keys F1 to F5*

16 *ECG signal input*

17 *Event marker button*

18 *Button to start and stop the recorder*

19 *Button to change the pacer output (current)*

20 *Button to change the pacer rate*

21 *Button to pause the pacer (without changing the settings)*

22 *Button to select the pacer mode (fixed rate, demand)*

23 *Button to unlock left battery for removal*

24 *Button to turn the pacemaker on and off*

25 *Indicator, yellow: blinks with each delivered pacing pulse*

26 *Button to open paper compartment*

27 *Battery with "Test" button and charge level indication*

28 *Indicator, green: is lit when defibrillator is powered from an external source (mains, ambulance)*

29 *Indicator, yellow*
blinking: left battery charging
on: left battery charged
off: left battery missing or partially charged, no external power source connected

30 *Indicator, yellow*
blinking: right battery charging
on: right battery charged
off: right battery missing or partially charged, no external power source connected

31 *STERNUM paddle*

Explanation of symbols used on the device

Consult accompanying documents

Caution, High Voltage

Type CF signal input: highly insulated, suitable for intracardiac application, defibrillation-proof

Type CF signal input: highly insulated, suitable for intracardiac application

Battery charging

Housing without battery (to close the battery slot)

Standby mode (line power operation)

Audio alarm OFF

Defibrillation Electrodes

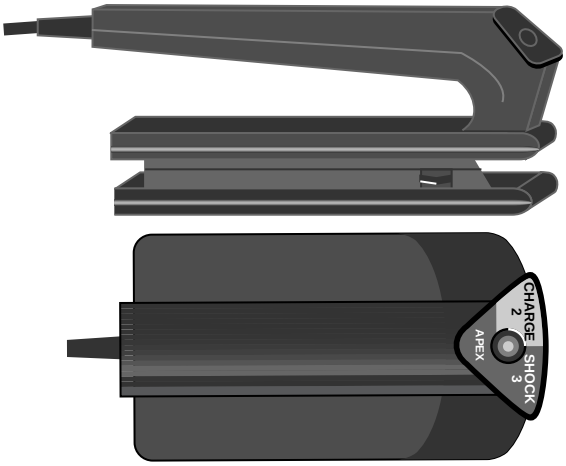


Figure 2-2. Hard paddle

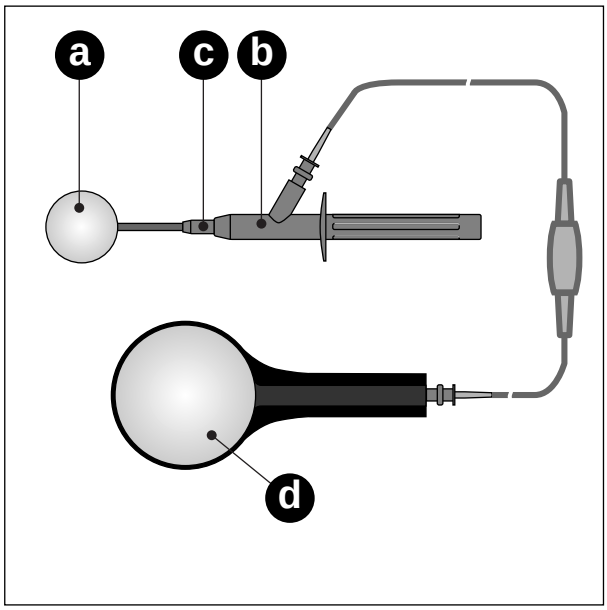


Figure 2-3. Electrode for internal defibrillation

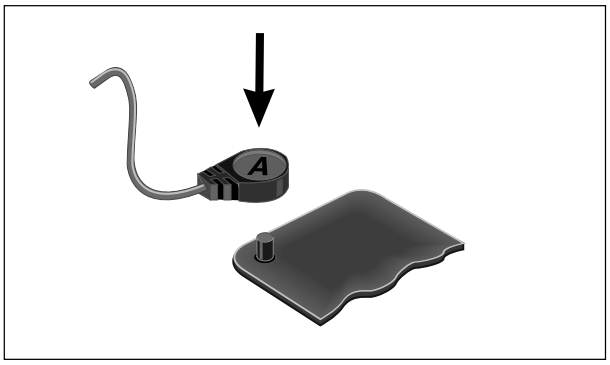


Figure 2-4. Disposable adhesive electrode (external defibrillation, pacing)

Hard Paddles

Hard paddles are the electrodes commonly used for external, transchest defibrillation. There is a special Apex paddle and a Sternum paddle.
For delivery of the defibrillation shock, the paddles are placed directly on the body surface. Before use, however, an ample amount of electrode gel must be spread onto the paddles.
Both paddles have a shock button: The shock button on the Apex paddle is used to initiate defibrillator charging; afterwards the defibrillation shock is triggered by pushing both shock buttons.
The paddles can also be used to acquire the ECG signal.
A smaller contact surface for defibrillation of children is integrated in the paddles (see "Defibrillation of Children" in section 4.2).

Electrodes for Internal Defibrillation

Electrodes for internal defibrillation consist of a contact spoon (**a**, Figure 2-3), a handle **b,** and a counter nut **c**.
The spoon must match the size of the heart and have full contact with the myocardium. There is a choice of 3 different spoon sizes.
The electrodes as well as their connection cable must be sterilized before each use.
An internal defibrillation is either performed with **two** spoon electrodes or with **one** spoon electrode and a so-called "external counter electrode" (**d**, Figure 2-3) which is placed under the patient and in the immediate vicinity of the heart.
Defibrillator charging and release of the defibrillation shock are initiated with buttons on the device.

Disposable Adhesive Electrodes

Disposable adhesive electrodes are used both for defibrillation and for pacing. These electrodes are self-adhesive and pregelled. They are connected by means of a special cable and may remain attached to the patient for a maximum of 24 hours.

3 Putting the Device into Operation and Performance Check

Safety information

Danger

Explosion Hazard – The device is not designed for use in areas of medically used rooms where an explosion hazard may occur. An explosion hazard may result from the use of flammable anesthetics, skin cleansing agents and disinfectants.
Also, it is not permitted to operate the defibrillator in an oxygen-enriched environment or in the presence of flammable substances (gas) or anesthetics.
Oxygenation in the vicinity of the defibrillation electrodes must be strictly avoided. Temporarily interrupt the oxygen supply.

Warning

Shock Hazard — Observe the following warnings. Otherwise the lives of the patient, the user and bystanders are in danger.

- ***The Marquette Responder® 3000 is a high-voltage electrotherapy device and must be handled by qualified and specially trained personnel. Improper use of the device can endanger life. Always follow the instructions given in the operator's manual.***
- ***When equipped with the AC power adapter, do not use the defibrillator outdoors because the power adapter is not splash-proof.***
- ***Before using the device, the operator must ascertain that it is in correct working order and operating condition. In particular, all connectors, electrodes as well as sensors and probes must be checked for signs of damage. Damaged parts must be replaced immediately, before use.***
- ***When disconnecting the device from the power line, remove the plug from the wall outlet first, before disconnecting the cable from the device. Otherwise there is a risk of coming in contact with line voltage by inadvertently introducing metal parts in the socket of the power cord.***
- ***As a general rule, utmost caution is advised for intracardiac application of medical technical devices. Great care must be exercised to prevent that conductive parts (connectors, electrodes, transducers) connected to the isolated patient signal input come in contact with other grounded conductive parts, as this could bridge the patient's isolation and cancel the protection provided by the isolated input.***

- ***Electrically conductive contact with parts connected to the heart (pressure transducers, metal tube connections and cocks, guide wires, electrode catheters and the metal parts of syringes) must be avoided at all cost. When using devices intracardially, observe these guidelines:***
- ***always wear isolating rubber gloves;***
- ***parts with a conductive connection to the heart must be isolated from ground;***
- ***do not use tube fittings and stopcocks made of metal, if possible;***
- ***when connecting the heart catheter, observe these guidelines:***
  - the connection must be isolated
  - all electrodes must be attached to the patient and secured against inadvertent disconnection or they must be isolated and protected against inadvertent contact (otherwise electrodes that become disconnected could bring the patient in contact with ground).
- ***When devices are used intracardially, the annual Technical Inspections are mandatory. During intracardiac application of medical electrical devices, a defibrillator and pacemaker, both checked for proper functioning, must be readily available.***
- ***Ensure that no conductive connection between the patient and bystanders exists during defibrillation.***

- ***The mains plug must be connected to an appropriate power supply with a non-fused earthed wire. If these requirements cannot be guaranteed, connect the device to the ambulance power supply or operate it on battery power.***
- ***Do not use multiple portable socket outlets (MPSO) to connect the device to the power line.***
- ***Devices may be connected to other devices or to parts of systems only when it has been made certain that there is no danger to the patient, the operators, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned or other informed experts as to whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of devices. Standards IEC 60601-1-1/EN60601-1-1 must be complied with in all cases.***
- ***The device (without AC power adapter) is suitable for application in a humid environment provided the regulations concerning drip-proof equipment of IEC 60601/EN 60601 are strictly observed. However, do not defibrillate patients in a very moist or wet environment, unless absolutely necessary. Always dry the defibrillation electrodes and connection cables prior to defibrillation.***

Warning

- ***Equipment Failure — Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the defibrillator comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems, and cellular telephones are a possible source of interference as they may emit higher levels of electromagnetic radiation.***
  Keep the defibrillator away from these devices and verify the defibrillator performance before use.
- ***Equipment Failure — Similarly, the defibrillator may disturb equipment operating in its vicinity when charging or delivering the shock. Verify the performance of these devices before use.***
- ***Suffocation Hazard — Dispose of the packaging material, observing the applicable waste-control regulations. Keep the packaging material out of children's reach.***

Caution

- ***Equipment Damage, Shock Hazard — Devices intended for emergency application must not be exposed to low temperatures during storage and transport to avoid moisture condensation at the application site. Wait until all moisture has vaporized before using the device.***
- ***Equipment Damage — Exercise great care when using HF surgery equipment on the patient at the same as the defibrillator. As a general rule, the distance between the ECG and defibrillation electrodes and the HF surgery electrodes should not be less than 15 cm. If this is not ensured, disconnect the electrodes and transducer leads while using the HF surgery device.***
- ***Equipment Damage — Avoid defibrillating repeatedly into open air or with the paddles shorted together, because the device temperature may increase to an inadmissible level due to the internal safety discharges.***

Literature

Medical Device Directive of August 2, 1994

EN 60601-1: 1990 + A 1: 1993 + A 2: 1995
Medical electrical equipment. General requirements for safety.

EN 60601-1-1: 9/1994 + A1: 12/1995
General requirements for safety. Requirements for the safety of medical electrical systems.

IEC-Publication 513/1994: Fundamental aspects of safety standards for medical equipment.

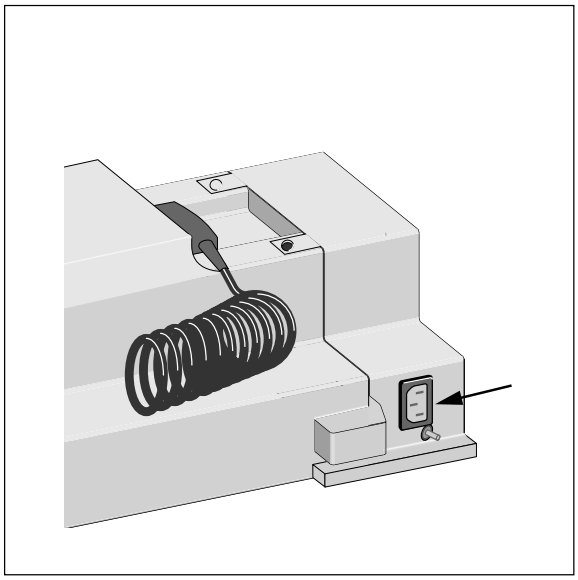


Figure 3-1. Defibrillator with AC power adapter

Note

The Marquette Responder® 3000 is switched on and off with the energy selector. Once you are familiar with the device operating routines, this control lets you turn on the device and select the required defibrillation energy in one action. No shock can be delivered in the position of the energy selector.

Power Supply

The defibrillator can be powered

- from the power line (requires AC power adapter, P/N 205 108 01, Figure 3-1),
- from the ambulance power supply system (requires vehicle mounting unit, P/N 202 317 01),
- from the wall mount unit (P/N 202 317 03)
- from 1 or 2 rechargeable batteries (mains-independent).

Batteries are recharged by one of the following methods:

- in the defibrillator, when the defibrillator is connected to the power line or to the ambulance power supply system, or
- by means of the separate charging unit ASU 3000 (P/N 701 279 01).

If you prefer to operate the device mains-independent, ensure that the batteries are charged (chapter 14 "Battery Power Operation").

Please refer to chapter 16 for information on operating the device in the vehicle mounting unit and on installing the AC power adapter.

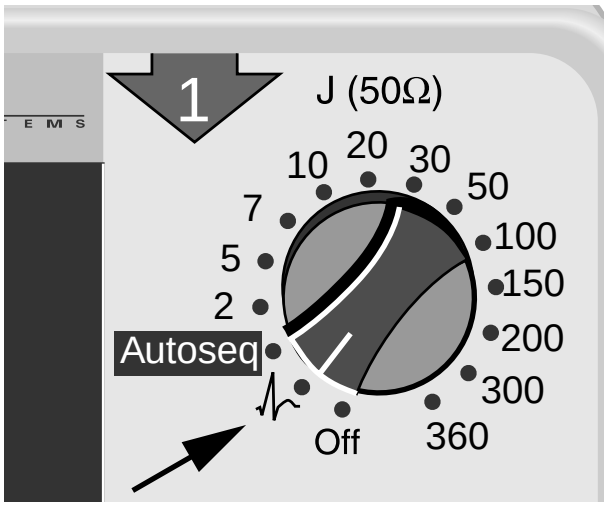


Figure 3-2. Turning the defibrillator on

Turning the Defibrillator On

- Connect the device to the power supply.
- Switch on the device by turning the energy selector to (defibrillation shocks cannot be delivered in this position).

The test screen appears and the device emits a short audio signal.

On the test screen you can see the software version and a message referring to the self-test. The three color blocks in red, green and blue are displayed to verify the correct representation of the colors.

After the self-test the standard screen appears (Figure 3-3).

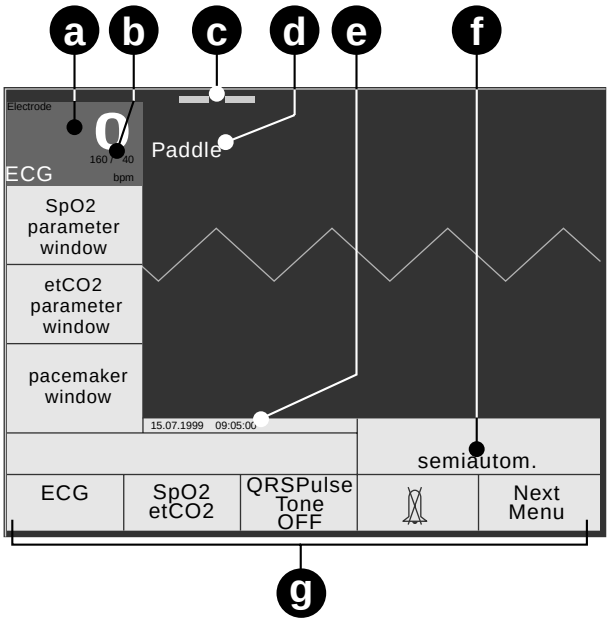


Figure 3-3. Standard screen display

***a** measured heart rate/pulse rate*

***b** selected limit values*

***c** battery charge level indication*

***d** ECG lead (ECG signal acquired via "Paddle")*

***e** date, time*

***f** selected operating mode, defibrillation energy*

***g** menu*

The Standard Screen Display

This is the information presented on the standard screen display:

- windows for heart / pulse rate, SpO_2 and $etCO_2$ readings including the limit values **a**, **b**
- battery charge level **c**
- ECG lead **d**
- window for ECG, SpO_2 and $etCO_2$ waveforms
- window indicating operating mode and defibrillation energy **f**
- date and time **e**
- menu **g**.

The color concept for the displayed information lets you see at a glance whether

- the parameter reading is within the alarm limits (green),
- a technical fault is reported (blue),
- an alarm is reported (red),
- the system displays a message (yellow).

If the device does not receive an ECG signal, the HR window is blue (technical fault) and a sawtooth signal is displayed instead of an ECG. The SpO_2 and $etCO_2$ parameter windows are also blank and the corresponding waveforms are missing when the required sensors are not connected.

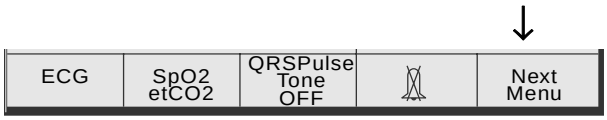


Figure 3-4. Main menu

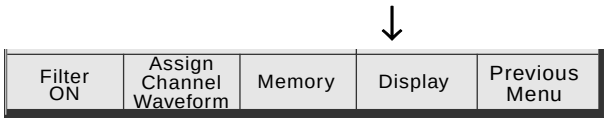


Figure 3-5. Main menu, page 2

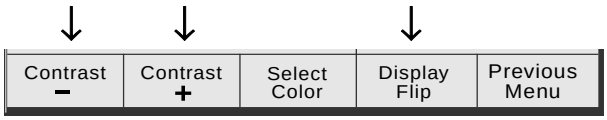


Figure 3-6. Display menu

Note

The main menu will automatically reappear, when no button is activated for a period of 30 seconds.

Note

Press F5 for about 2 seconds to return directly to the main menu.

Note

Enter your own settings in the column at the far right (with date and signature).

Display Flip

The screen display can be rotated 180° to adapt it to the operating position of the defibrillator. The display can be flipped permanently from the setup menu or temporarily as outlined below. You can also set up the system to flip the display automatically when the defibrillator is inserted in the vehicle mounting unit (chapter 13 "Defibrillator Setup").

- In the main menu, select **F5** [Next Menu] (Figure 3-4).

You will see page 2 of the main menu (Figure 3-5).

- Display the Display menu with **F4** [Display] (Figure 3-6).
- To flip the display, press **F4** [Display Flip].

Contrast adjustment

- Adjust the contrast from the Display menu with **F1** and **F2**.

Adjusting Maximum Contrast (Select Color)

- Adjust the maximum contrast from the Display menu with **F3**.
- Press **F5** [Previous Menu] for about 2 seconds to return directly to the main menu.

System Setup

The device has a configuration menu which allows you to customize some of the functions to suit your personal requirements. These settings will be retained. The table at right shows all device settings for which customer defaults can be selected, as well as the factory defaults.
The information given in this manual is based on a defibrillator with the factory defaults.
In chapter 13 "Defibrillator Setup" you will find instructions on setting up the defibrillator. The same chapter explains how to change the language and how to restore the factory defaults.

Parameter	Comment	Factory Defaults	Options	User Setup
ALARM LIMITS				
HR Limit		40/160	OFF, 15 to 300 increments of 5	
SpO_2 Limit		---/90	OFF, 60 to 99	
$etCO_2$ Limit		---/20	OFF, 5 to 76 increments of 1	
ECG				
Print on Alarm	autom. recorder start on violation of limit value	off	on/off	
Lead Fail Alarm	audio signal indicating disconnected electrode	off	30 s/off	
Alarm Tone	audio signal indicating violation of an alarm limit	off	on/off	
QRS Beep		off	low/middle/high / off	
Muscle Filter	suppression of motion artifact	on	on/off	
Gain	for ECG display	1 cm/mV	0.5; 1; 2 cm/mV	
Lead Channel 1		I	standard leads, paddle acquisition	
Lead Channel 2		II	standard leads, SpO_2	
Lead Channel 3		III	standard leads, SpO_2, $etCO_2$	
DEFIB				
Print on shock	automatic recorder start on shock	on	on/off	
Operating Mode**	choice of the operating mode	semiautomatic/button	semiautom./button semiautom./password semiautom. manual	
Autosequence	energy selection	200 J, 200 J, 360 J	150 to 360 J per shock	
Pacemaker	default pacer rate	60 P/min	30 to 200 P/min	
SpO_2				
C-LOCK	C-Lock ECG synchronization	off	on/off	
SpO_2 Integ. Time	SpO_2 integration time	8 s	4 s, 8 s, 12 s	
DATE/TIME**	Change clears all existing settings.			
Date Format**		day.mon.year	day.mon.year mon/day/year	
Entry of date and time				
DEVICE				
Display	screen display (SmartFlip = display flips automatically when defibrillator is placed in vehicle mounting unit)	normal	normal, reverse, SmartFlip	
Volume	valid for all audio signals	high	high/low/middle	
Cont. Printout	continuous recording or 14-second strip	off	on/off	
Analysis	continuous ECG analysis	on	on/off	
AC Line Filter**	elimination of AC line interference	50 Hz	off/50 Hz/60 Hz	
Language**	selection of the language	—	—	
Factory Default	restores factory defaults	—	—	
User**	text or name (20 characters)	—	—	
PASSWORD**	entry of the password	111	000/999	
for config**	protects access to configuration menu	off	on/off	
EVENT TEXTS**	entry of event texts	—	—	
BATTERY	battery maintenance program	—	on/off	
OPTIONS	entry of option code to unlock option	—	—	

** not affected by reactivation of factory defaults

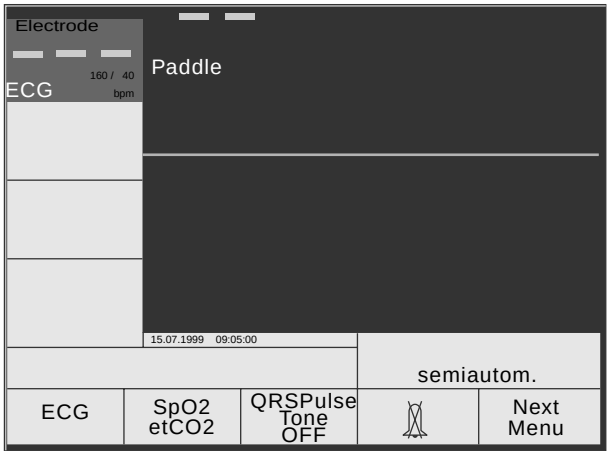


Figure 3-7. Standard screen display of a defibrillator ready for operation (no ECG, SpO_2 and $etCO_2$ signal available)

Note

A special simulator is required to test the defibrillator performance in the semiautomatic mode.

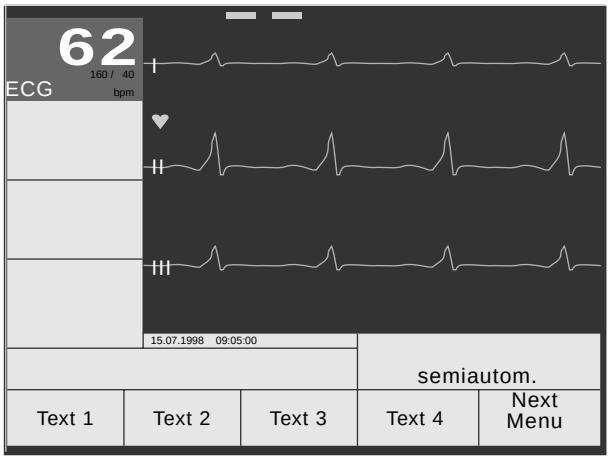


Figure 3-8. Event texts

Performance Check

A performance check must be carried out before each use.

The check includes:

- a visual inspection of the device, the cables and the electrodes for signs of mechanical damage,
- verification of the functional readiness of the device,
- delivery of a test discharge.

After power-up and during operation, the Marquette Responder® 3000 runs automatic self-tests. If malfunctions are identified, an error message will be displayed (see chapter 17 "Error and System Messages"). In this situation do not put the device into service.

In all other cases you will see the standard screen display (Figure 3-7) and the device is ready for use.

Now verify that the defibrillation shock is correctly delivered by triggering a test discharge (chapter 15 "Test Discharge").
If the energy of the test discharge is not within the specified limits, a defibrillation is possible all the same (it is the user's decision whether or not to employ the defibrillator). However, the device must be immediately checked and repaired by a service technician.

Event Button

You can use the Event button to mark specific events (e.g. administration of medications). When you press this key, the corresponding point in time is earmarked in the full-disclosure ECG. Furthermore, you can assign a maximum of 8 "event" texts to the function keys **F1** to **F4** (e.g. names of medications). When you press Event these texts appear in the menu line (Figure 3-8). You can press one of the function keys to assign the corresponding text to the event. With **F5** Next Menu you can display the next line of 4 texts. (Refer to chapter 13 "Device Setup" for instructions on entering event texts.)

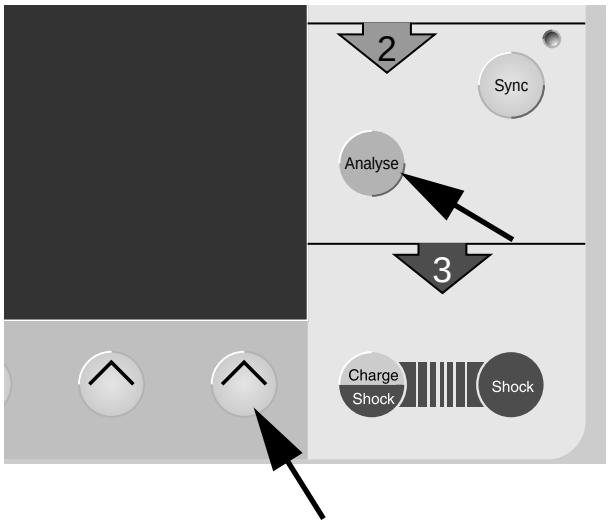


Figure 3-9. Buttons to activate the manual mode

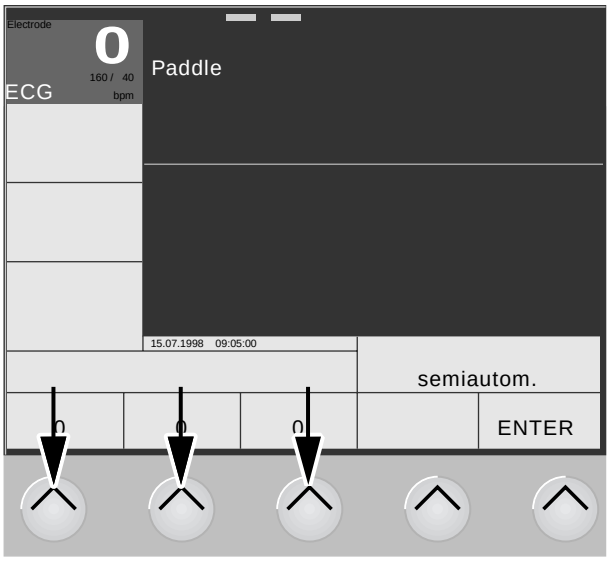


Figure 3-10. Buttons for entry of the password

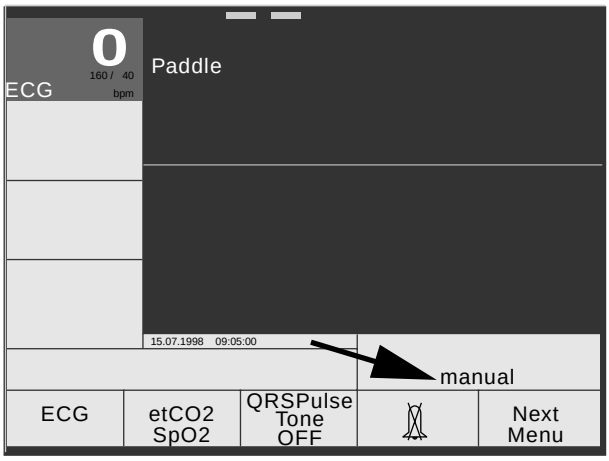


Figure 3-11. Defibrillator set up for manual operation

How to toggle the defibrillator from semiautomatic to manual operation

Depending on their setup, semiautomatic defibrillators can be switched to manual control. The defibrillator can be set up for four different modes of operation:

– semiautom./button (switching to manual mode by activating button)

– semiautom./password (switching to manual mode by activating button and entering password)

– semiautomatic (manual control not possible)

– manual (only manual control possible)

Operating Mode "semiautomatic/button"

- To activate the manual mode, simultaneously press **F5** and Analyse (Figure 3-9).

When switched on again, the defibrillator will reactivate the operating mode selected in the setup menu.
Date and time of the change of operating modes is stored in the event memory.

Operating Mode "semiautomatic/password"

- To activate the manual mode, simultaneously press **F5** and Analyse (Figure 3-9).

The screen for entry of the password appears (Figure 3-10).

- Enter the password (3-digit number) with ***F1, F2, F3.*** The factory-set password is 111 (also refer to chapter 13, section "Password").

When switched on again, the defibrillator will reactivate the operating mode selected in the setup menu.
Date and time of the change of operating modes is stored in the event memory (chapter 11 "Memories of the Marquette Responder® 3000").
If you wish to return to the semiautomatic mode, you will have to turn the device off and on again.

4 Manual Defibrillation

4.1 Defibrillator Application Guidelines

Observe the following guidelines to ensure successful and safe defibrillation. Otherwise the lives of the patient, the user and bystanders are in danger.

Warning

- ***Defibrillating a patient with normal heart rhythm may induce ventricular fibrillation.***
- ***Position the patient flat on a hard surface where he is electrically insulated. The patient must not be allowed to come into contact with metal parts, e.g., bed or litter, to prevent unwanted pathways for the defibrillation current which may endanger the assistants. For the same reason, do not position the patient on wet ground (rain, accident in swimming pool). Do not allow the defibrillation electrodes to come into contact with other electrodes or metal parts which are in contact with the patient.***
  The patient's chest must be dry, because moisture can cause unwanted pathways for the defibrillation current.
  After use of flammable skin cleansing agents, wait until they have completely dried.
- ***The operator and all assistants must be briefed regarding the preparations for and execution of defibrillation.***
  All tasks must be clearly assigned.
  Immediately prior to the shock
  - ***interrupt heart massage and artificial respiration,***
  - ***disconnect tube connections, and***
  - ***warn bystanders.***
- ***Ensure that no conductive connection between the patient and bystanders exists during defibrillation.***
- ***Before delivering the shock, verify that the charged and selected energies are the same.***
- ***Shock Hazard — Always switch off the device before exchanging the defibrillation electrodes.***

- ***Pacemaker Patients — Defibrillating a patient with an implanted pacemaker is likely to impair the pacemaker function or cause damage to the pacemaker.***
  For this reason
  - ***select the smallest energy level possible for the application,***
  - ***do not apply the defibrillation paddles in the vicinity of the pacemaker electrodes,***
  - ***have an external pacemaker at hand,***
  - ***check the implanted pacemaker for proper functioning as soon as possible after the shock.***

Caution

- ***Equipment Damage — Disconnect transducers and devices that are not defibrillation-proof from the patient before delivering the shock.***
- ***Equipment Damage — Do not defibrillate the patient with a second defibrillator, while defibrillation electrodes (paddles, pads) of the first device are applied.***
  If the use of a second defibrillator is inevitable, disconnect the electrodes from the first device or remove them from the patient.

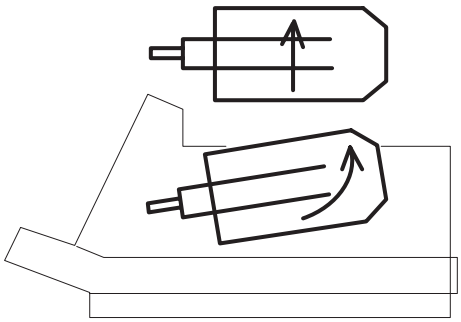


Figure 4-1. Removing the paddles

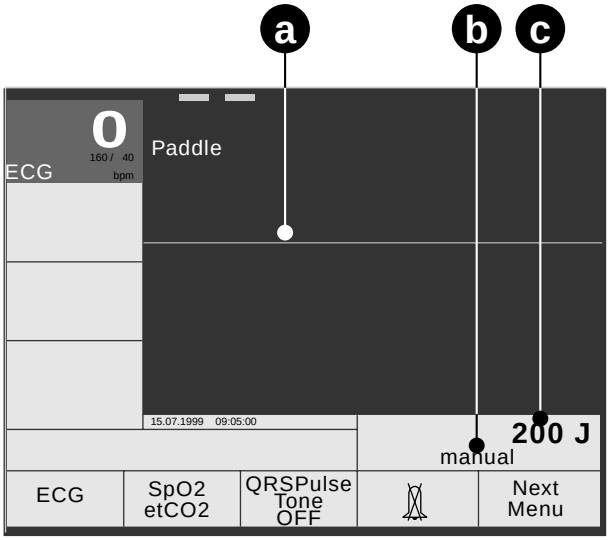


Figure 4-2. Power-up screen (paddles connected)
***a** ECG signal acquired via "Paddle"*
***b** manual mode*
***c** selected energy*

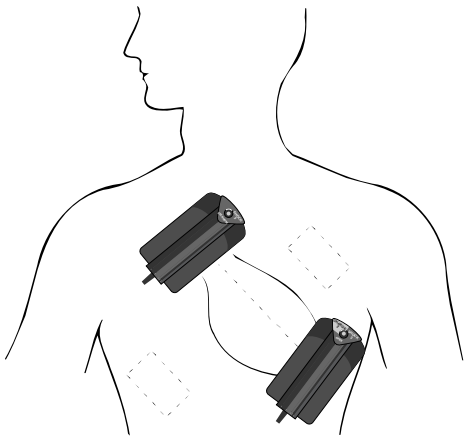


Figure 4-3. Paddle application points (dashed application points for pacemaker patients)

4.2 Non-Synchronized Defibrillation

Using Paddles

- Remove the paddles from their compartments as shown in Figure 4-1.
- Carefully dry the paddles and the handles in particular, if they are wet.
- Apply an ample amount of electrode cream to the paddle surfaces.
- Set the energy selector to "Autoseq" or to the required energy level.

In the "Autoseq" position of the energy selector, the defibrillator automatically sequences the preset defibrillation energy levels. The level for the 3rd shock is maintained for all subsequent defibrillations. When you set the energy selector again to "Autoseq", the automatic charge sequence starts over.
The factory set Autosequence energy levels are the values recommended by AHA/ERC for ventricular fibrillation and pulseless tachycardia.
1st shock with 200 J
2nd shock with 200 J
3rd and all subsequent shocks with 360 J.

- Check that the selected energy is displayed (**c**, Figure 4-2).
- Apply the paddles on the patient's thorax such that the greatest possible amount of energy flows through the myocardium. The imaginary line connecting the paddle centers should be identical with the cardiac median line (Figure 4-3).
- Press the paddles firmly onto the thorax (the ECG appears on the monitor screen).
- Do not touch the patient any more and warn all those present.

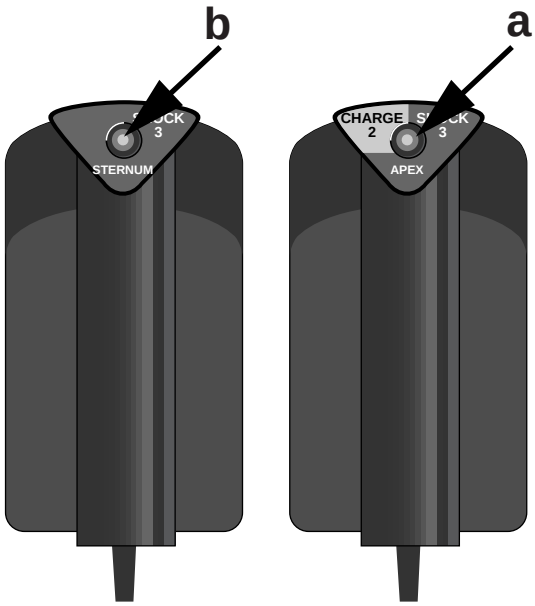


*Figure 4-4. Buttons to initiate defibrillator charging (**a**) and to trigger the shock (**a**+**b**)*

Warning

Risk of Skin Burns / Equipment Damage — Do not apply the paddles over

- ***sternum or clavicle,***
- ***nipples***
- ***implanted pacemaker or defibrillator devices.***

Note

– ***If you do not trigger the shock within 30 seconds of charging, the energy will automatically be discharged internally. You will then have to recharge the defibrillator.***

– ***When the defibrillator is charged, you can increase and decrease the energy level to any value with the energy selector (without pressing the "Charge" button again).***
For an internal discharge of the stored energy, set the energy selector to or to "Off".

- Initiate energy storage with the button on the APEX paddle (**a**).

When the selected energy is stored,

– the device emits an audio signal
– the message "Energy available" appears,
– the available energy is displayed (if the available energy drops below a given level, the defibrillator recharges automatically).

- Now trigger the shock within 30 seconds. To do so, simultaneously press the buttons **a** and **b** on the paddles.

After the shock

– the audio signal stops and the delivered energy is displayed for approx. 6 seconds (in place of the available energy),

– the recorder prints a 14-second ECG strip (4 seconds before the shock, 5 seconds blanked, 10 seconds after the shock) (configurable); the blanked period of time is indicated by a vertical line on the recording;

– the shock delivery is annotated on the stored ECG (also refer to chapter 11 "Memories of the Marquette Responder® 3000").

If the defibrillator cannot store the selected energy so that selected and stored energy values differ, a warning will be displayed. The defibrillation pulse can be triggered all the same.

In this situation we recommend to check the batteries first. If the batteries are intact, have the defibrillator immediately repaired.

Shock Counter

The number of delivered shocks is indicated below the energy value.

This counter is reset to 0 when you set the energy selector to .

The number of delivered shocks is also shown on the recording strip (Figure 5-5, intervention report **d**). This counter, however, counts all shocks since the device was turned on and is reset to 0 only when the device is turned OFF.

Ending Therapy

- Once therapy has ended, set the energy selector to for continued monitoring of the patient.
- If there is no need to monitor the patient, switch off the defibrillator by setting the energy selector to "Off".
- Clean the paddles and the device as outlined in chapter 18 "Cleaning, Maintenance".

Defibrillation of Children

Warning

Damage to Myocardium — Please note that children require less energy for successful ventricular defibrillation than adults. For the first defibrillation shock delivered to babies and small children, select an energy of approx. 2 J/kg body weight. For subsequent shocks, the energy may be increased to 4 J/kg body weight.

Risk of Skin Burns — The full electrode must be in contact with the skin surface (use the small contact surface of the paddles / pads for children).

The paddles have two different contact surfaces; a large one (can be removed) for the defibrillation of adults and a smaller one for the defibrillation of children.

Remove the large contact surface for pediatric use:

- Press on the lock button **1** (Figure 4-5).
- Slide the contact surface **2** towards the front and take it off the paddle.
- When re-installing it, the large contact surface must audibly click into place.

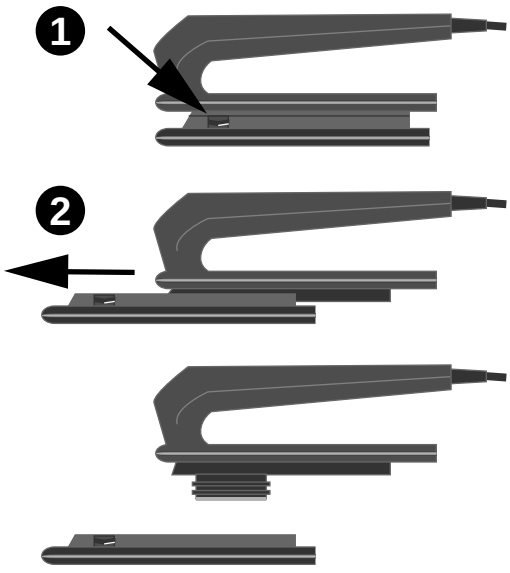


Figure 4-5. Removing the large contact surface from the paddles

Using Disposable Defibrillation Pads

Danger

Shock Hazard — For defibrillation with disposable adhesive electrodes, the paddles including their leads must be replaced with the adapter cable 223 383 01. Switch off the defibrillator before exchanging the lead. Also, the defibrillator must be switched off when the adapter cable is connected to the pads.

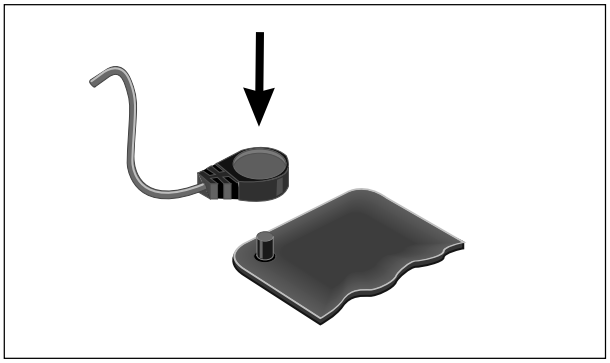


Figure 4-6. Connecting the lead

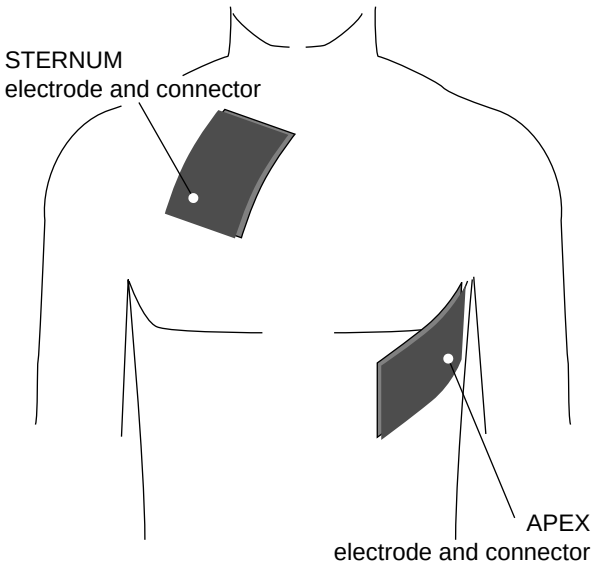


Figure 4-7. Defibrillation pad application points (anterior - anterior)

– Use pads before their expiration date.

– Do **not** reuse the pads.

– A pair of pads may remain attached to the patient for up to 24 hours and withstands up to 50 shocks of 360 J each.

– Use electrodes 919 202 94 for adults and electrodes 919 202 95 for children.

– Shave the application points; this improves conductivity and makes removal of the pads easier.
STERNUM: right sternal edge at the level of the 2nd intercostal space,
APEX: left axillary line at the level of the 5th intercostal space (Figure 4-7).

– Place the pads on the patient such that the connectors point to either side of the patient and that the cables are not hindering patient treatment.

– The electrodes are pregelled; therefore, do not use additional contact cream or gel.

– Do not use pads, if the gel is dry.

- Rub the patient's chest dry.
- Press the connector of the lead on to the electrode contact pin until you hear it click into place (Figure 4-6).
- Peel off the backing from each pad.
- Press the pads carefully on the appropriate sites, observing the APEX and STERNUM labels (Figure 4-7).

Warning

Risk of Skin Burns / Equipment Damage — Do not attach the pads over

- ***sternum or clavicle***
- ***nipples***
- ***implanted pacemaker or defibrillator devices.***

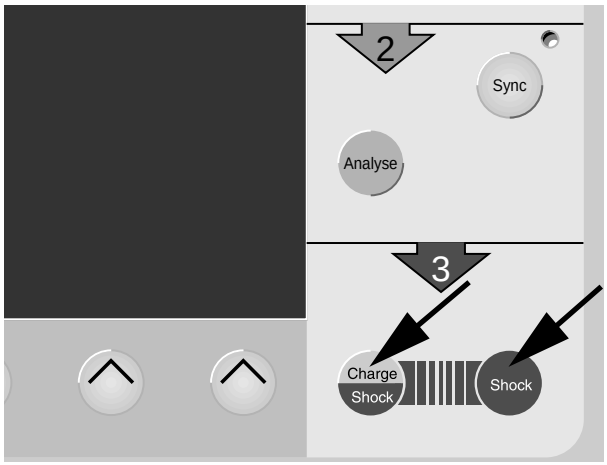


Figure 4-8. Buttons to initiate defibrillator charging and to trigger the shock

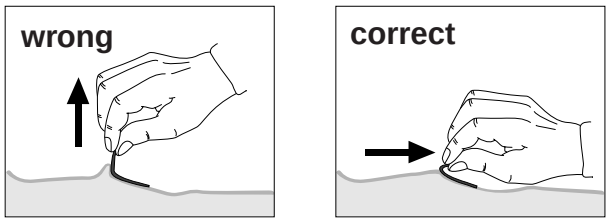


Figure 4-9. Removing the pads

- Before delivering the shock, check that the pads are firmly seated.
- Defibrillate the patient as described for defibrillation with paddles (page 19).
  Be sure to charge the defibrillator with Charge Shock and to deliver the shock by simultaneously pressing the buttons Charge Shock **and** Shock (Figure 4-8).
- Carefully remove the electrodes after use (Figure 4-9) and discard them immediately.

Note

Discard disposable pads immediately after use. Do not reuse them.

Note

If you are using internal electrodes with the Marquette Responder® 3000, defibrillator charging must be initiated with button Charge Shock and the shock is delivered by simultaneously pressing buttons Charge Shock and Shock.

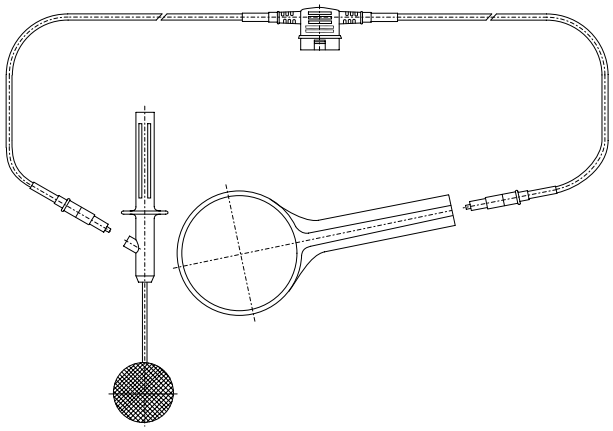


Figure 4-10. External counter electrode

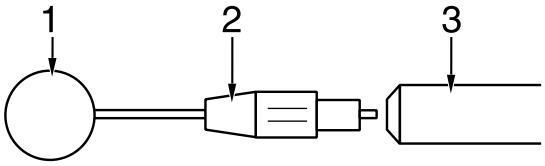


Figure 4-11. Inserting the spoon electrode

Using Internal Defibrillation Electrodes

Warning

Shock Hazard – Always switch off the device before exchanging the defibrillation electrodes and internal spoons.

Spoon-shaped electrodes are used for internal defibrillation. Their contact surface must match the dimensions of the heart. The spoons must make full contact with the heart. There is a choice of 3 different spoon sizes. You can use either two spoon electrodes or one spoon electrode and one external counter electrode for defibrillation (Figure 4-10, chapter 20 "Order Information"). Sterilize internal electrodes before each use (chapter 18 "Cleaning, Maintenance").

Inserting the Spoon Electrode

- Screw the counter nut **2** (Figure 4-11) onto the electrode as far as it will go.
- Screw the contact paddle **1** into the handle as far as it will go, then bring it into the appropriate position.
- Now fix the contact paddle by screwing the counter nut **2** tight against the handle **3**.

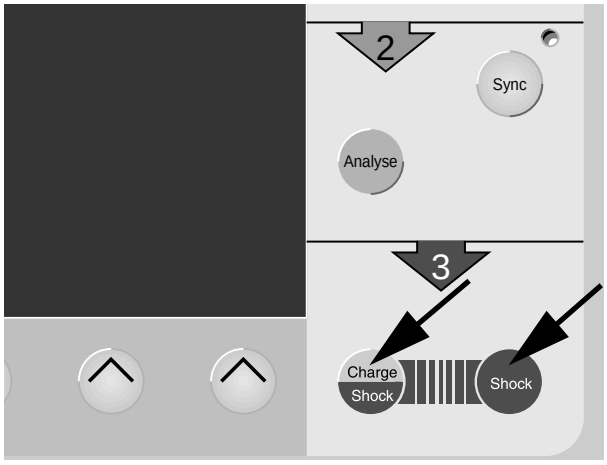


Figure 4-12. Buttons to initiate defibrillator charging and to trigger the shock

Defibrillating the Patient

With internal electrodes, it is not possible to select a value above 50 Joules, because higher energies may damage the myocardium. When you set the energy selector to a value above 50 Joules, you will be alerted by a message and defibrillator charging will not proceed.

- Defibrillate the patient as described for defibrillation with paddles (page 19).
  Be sure to charge the defibrillator with Charge Shock and to deliver the shock by simultaneously pressing buttons Charge Shock **and** Shock (Figure 4-12).

4.3 Synchronized Defibrillation (Cardioversion)

Some Basic Facts

Warning

False Triggering — Do not use a pacemaker ECG for triggering, because the trigger pulses derived from pacemaker ECGs may be incorrect and synchronized delivery of the defibrillation shock may not be possible.

Note

After each synchronized defibrillation, the device reverts to the non-synchronized mode; the same applies when the energy selector is set to .

For synchronized defibrillation (cardioversion) the defibrillation shock is delivered in synchronization with the heart action, as the heart is still working. As a prerequisite, the patient's ECG signal must be supplied to the defibrillator. After the attending physician has given the "defibrillation command" by pressing the appropriate buttons, the device will wait for the next QRS complex to derive the trigger signal for actual delivery of the shock.

The following electrodes can be used for cardioversion:
- paddles (+ separate ECG electrodes),
- adhesive electrodes (pads), or
- internal electrodes (+ separate ECG electrodes).

Indications

Examples
- mitral stenosis
- left ventricular hypertrophy (aortic stenosis, hypertension)
- impaired myocardiac function (ischemia, right heart failure)
- patients with atrial or ventricular arrhythmias, hypotension and/or pulmonary edema.

If ventricular fibrillation develops, select the non-synchronized mode for defibrillation, because it is not possible to detect a QRS complex for triggering in the presence of ventricular fibrillation.

Cardioversion with the Marquette Responder® 3000 is only possible in the manual mode.

We recommend acquiring the ECG with separate ECG electrodes. However, you can also defibrillate the patient with adhesive pads and pick up the ECG via the pads.

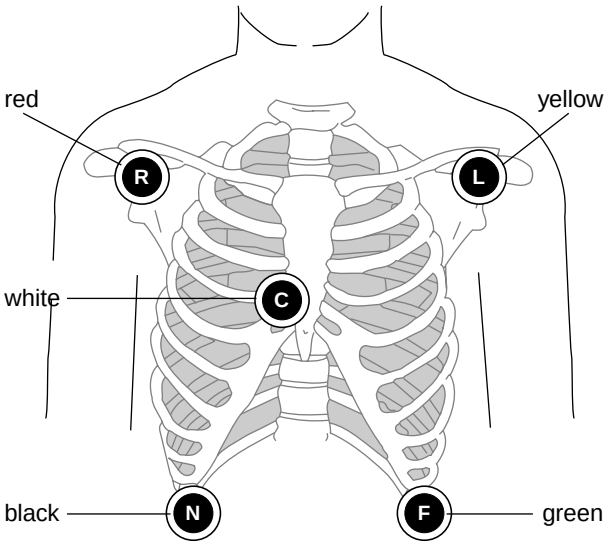


Figure 4-13. ECG electrode placement

Figure 4-14. Connecting the electrode leads to the patient cable

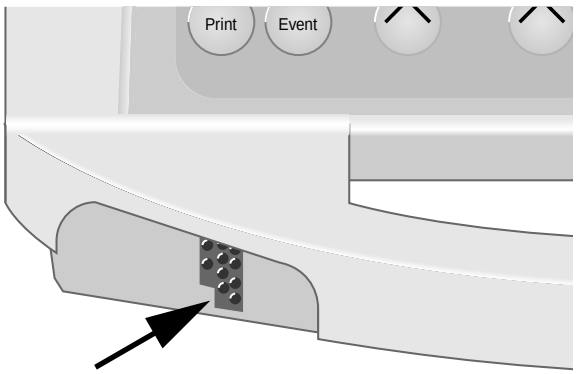


Figure 4-15. ECG signal input

Note

The 3-lead patient cable cannot be used with this defibrillator.

ECG Acquisition via Separate ECG Electrodes and Patient Cable

Use only silver/silver-chloride electrodes to acquire the ECG signal. These electrodes prevent polarization voltages which may be caused by the defibrillation shock, resulting in an ECG trace on the monitor screen or recording that simulates cardiac arrest. The ECG can be picked up with 5 or with 10 electrodes (for ECG measurement, however, 10 ECG electrodes are required (chapter 8)).

- Apply the electrodes as shown in Figure 4-13.
- Plug the block of leadwires (N, R, L, F, C1) into the patient cable (Figure 4-14).
- Connect the patient cable to the device (Figure 4-15).
- Turn on the device (energy selector to).

On the monitor screen you will now see the 3 ECG leads selected in the setup menu (factory defaults: leads I, II, III).

Warning

Shock Hazard / Equipment Damage — All patient signal inputs labeled with the symbol are protected against damage resulting from defibrillation and electrocautery voltages. For this reason, patient safety and device protection are ensured during defibrillation and HF surgery.

Nevertheless, extreme care should be exercised when electrosurgery devices are used on a patient who is connected to other devices. As a general rule, a minimum distance of 15 cm between the ECG and electrosurgery electrodes should be maintained. If this is not ensured, temporarily disconnect the electrodes and transducer leads while using the electrosurgery device.

Great care must be exercised to prevent that conductive parts (connectors, electrodes, transducers) connected to the isolated patient signal input come in contact with other grounded conductive parts, as this could bridge the patient's isolation and cancel the protection provided by the isolated input. It is particularly important that the neutral electrode does not come in contact with ground.

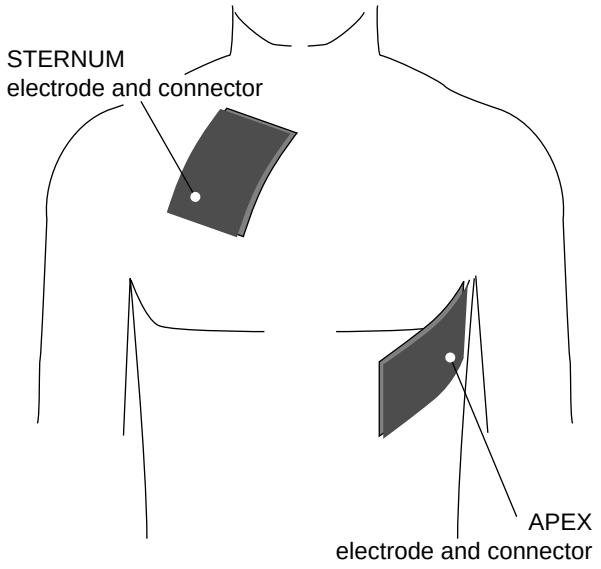


Figure 4-16. Defibrillation pad application points

ECG Acquisition via Defibrillation Pads

- Apply the defibrillation pads as shown in Figure 4-16.
- Turn on the device (energy selector to).

The ECG signal is now acquired via the pads and will automatically be displayed in channel 1 (unless a patient cable is connected).

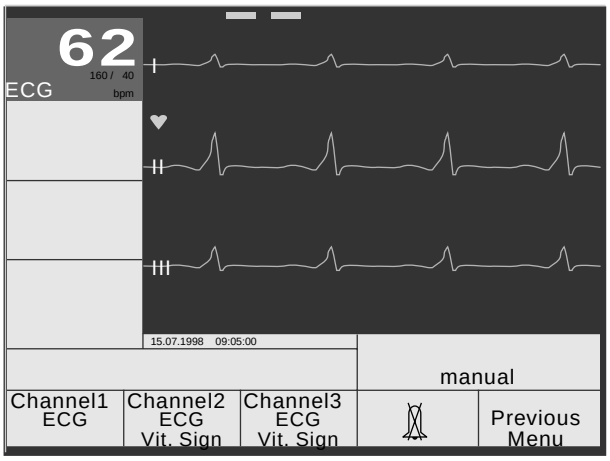


Figure 4-17. Menu for selection of the displayed ECG leads

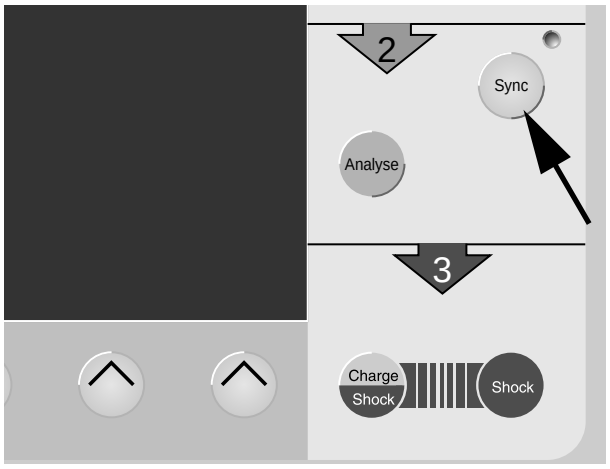


Figure 4-18. Sync button, activates the synchronized defibrillation mode

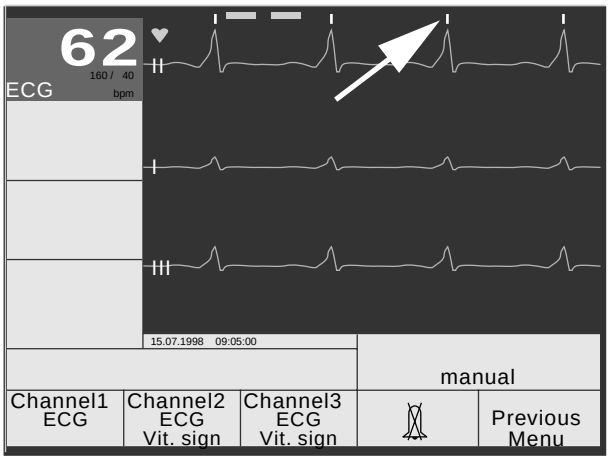


Figure 4-19. SYNC marker above QRS complex

Performing Cardioversion

- Check the ECG.

The ECG signal must be interference-free and have an adequate amplitude. Follow these steps to select another lead (only possible when the ECG is acquired via separate ECG electrodes) or to change the signal size:

  – Press **F1** [ECG].

  – Press **F1** [I...III, aV...V, Paddle] again.
  The menu for selection of the ECG lead appears (Figure 4-17).

  – Using **F1**, select the lead to be displayed in channel 1, with **F2** select the lead for channel 2, and with **F3** select the lead for channel 3 (with each key press the device advances to the next lead).

  – Press **F5** [Previous Menu] and change the signal size with **F2** [1 cm/mV].

  – Press **F5** [Next Menu] for about 2 seconds to return to the main menu.

- Activate the synchronized mode with Sync (Figure 4-18).
- Verify that
  – the heart symbol blinks regularly,
  – a SYNC marker appears above each QRS complex (Figure 4-19), and
  – the yellow indicator above the Sync button briefly goes off with each trigger pulse.
- Set the energy selector to the required energy level ("Autoseq" is not suitable for cardioversion).

> **Note**
>
> ***For cardioversion, AHA and ERC recommend the following energy levels:***
> ***50 J, 100 J, 200 J, 300 J, 360 J.***

- Defibrillate the patient as described on page 19. When using adhesive pads, please note that defibrillator charging is initiated with Charge Shock and the shock is triggered by simultaneously pressing Charge Shock **and** Shock.

5 Semiautomatic Defibrillation

Safety Information

In addition to the defibrillation guidelines set forth in chapter 4, please observe the following information: Failure to do so may compromise the success of the defibrillation or endanger the patient's life.

Warning

- ***Semiautomatic defibrillation is only permitted for patients with a body weight of at least 35 kg, who are unconscious, have no respiration and no pulse.***
- ***Although the arrhythmia detection algorithm yields good results, we cannot entirely exclude false analysis in specific situations. Therefore the user is obliged to make certain that the conditions for use of a semiautomatic defibrillator are met: unconsciousness, no respiration, no pulse. For the same reason, the user is entirely responsible for delivery of the defibrillation shock.***
- ***Do not use the anterior-posterior electrode placement.***
- ***In the semiautomatic mode, the defibrillator cannot deliver synchronized shocks.***
- ***For semiautomatic defibrillation, do not analyze the ECG during HF surgical interventions.***

Caution

- ***When used on pacemaker patients, the device may fail to make correct recommendations for delivery of a shock. Defibrillate pacemaker patients following the guidelines applicable in your institution.***
- ***During ECG analysis interrupt CPR measures, do not touch the patient and ensure that the patient does not move. Otherwise artifacts may adversely influence the analysis.***
- ***In the semiautomatic mode, defibrillator charging cannot be initiated manually.***

Some Basic Facts

On the control panel of the semiautomatic defibrillator there is one additional button: Analyse .

In the semiautomatic mode, an arrhythmia detection program scans the patient's ECG to check whether or not a shockable rhythm exists. If a shockable rhythm is found, the unit recommends defibrillation and automatically starts charging. In this operating mode, conventional control of the defibrillator is not possible (charging cannot be initiated manually).

The semiautomatic mode is thus suitable for persons who are not legally permitted to utilize a manual defibrillator (e.g. persons with insufficient knowledge of ECG analysis).

Observe the recommendations published by the AHA (American Heart Association) and the ERC (European Resuscitation Council).

In the semiautomatic mode, the defibrillator will start analyzing the ECG when the Analyse button is pressed. If the analysis algorithm detects ventricular flutter (> 120 bpm), ventricular fibrillation or ventricular tachycardia with a deviating QRS morphology, the defibrillator

– displays a message,
– starts charging, and
– informs the user when it is ready to deliver the shock.

The energy selector must be set to the "Autoseq" position, where the defibrillator automatically sequences the energy levels preset for the first three shocks. The factory default setting is the sequence recommended by AHA/ERC: 200 J, 200 J, 360 J. You are free, however, to select the energy levels for the Autosequence shocks from the following values: 150 J, 200 J, 300 J, 360 J.

If you do not set the energy selector to "Autoseq", an error message will be displayed. The message is cleared when

– you select "Autoseq" or
– switch to the manual operating mode.

It is recommended to acquire the ECG signal for analysis via the disposable defibrillation pads. ECG electrodes can be used as well. Paddles should not be used because they are likely to induce artifact.

Note

The analysis algorithm only responds to shockable arrhythmias.

Literature (at the time of printing)

Guidelines for Resuscitation, European Resuscitation Council (1998), ISBN 0-444-82957-1

Handbook of Emergency Cardiac Care, American Heart Association (1996), ISBN 0-8151-0885-0

"The Arrhythmia Detection Program" in the appendix of this manual.

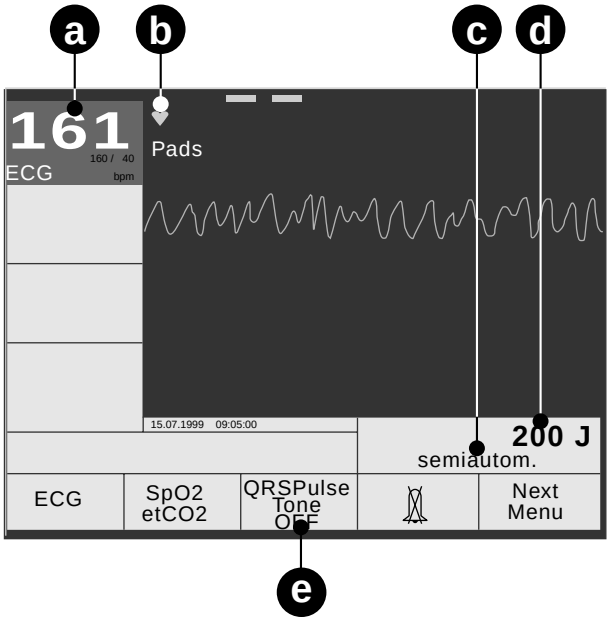


Figure 5-1. Standard display
***a** Heart rate*
green = HR detection OK
blue = lead failure
red = medical alarm
***b** QRS blip*
***c** semiautomatic mode selected*
***d** selected energy*
***e** menu*

Defibrillating the Patient in the Semiautomatic Mode

We recommend to defibrillate the patient with disposable adhesive pads in this mode. Thus, you only have to apply two electrodes, because the ECG signal can also be acquired via the pads.

If you are using separate ECG electrodes, please refer to the end of this chapter.

- Apply the defibrillation pads as described on page 22.
- Before delivering the shock, check that the pads are firmly seated.
- Set the energy selector to "Autoseq".
- Check that the semiautomatic mode is enabled (**c**, Figure 5-1) and that the selected energy is displayed (**d**, Figure 5-1).

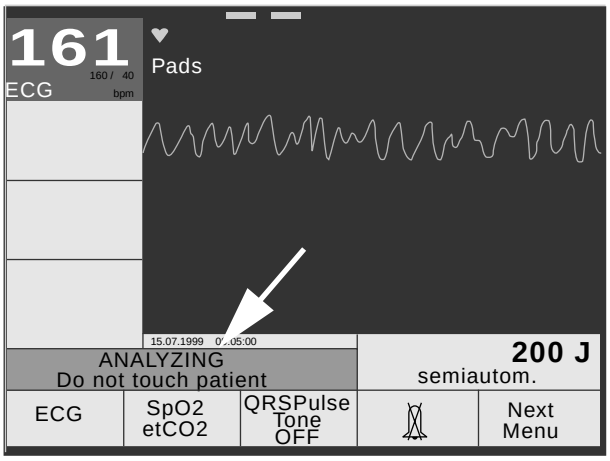


Figure 5-2. Message indicating that the ECG is being analyzed

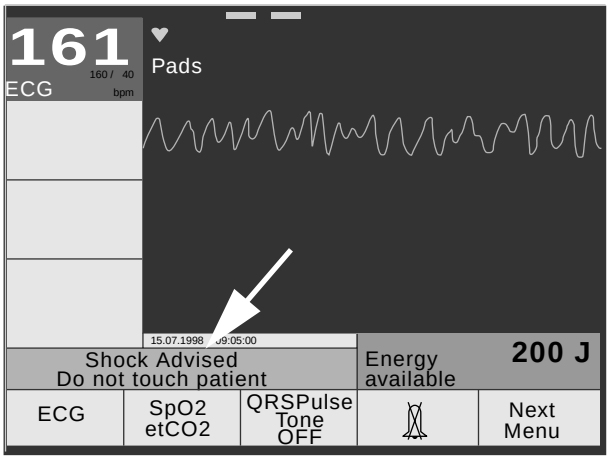


Figure 5-3. "Energy available" message and indication of charged energy

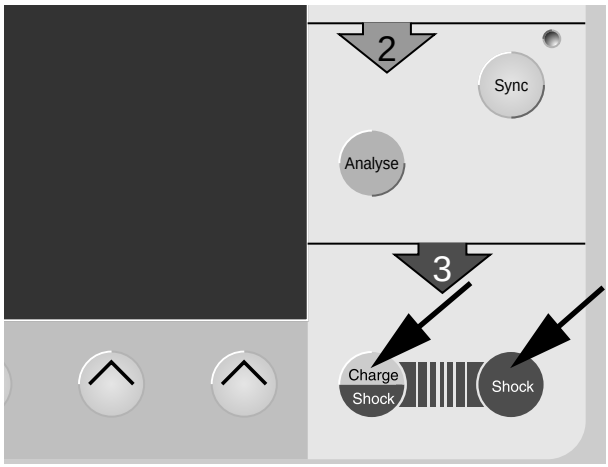


Figure 5-4. Buttons to deliver the shock

- Do not touch the patient any more and warn all those present.
- Press Analyse to initiate ECG analysis.

You will see the message "ANALYZING Do not touch patient" (Figure 5-2).

If the analysis algorithm detects ventricular flutter (> 120 bpm), ventricular fibrillation or ventricular tachycardia with a deviating QRS morphology, the defibrillator

– displays the message "Shock advised - Do not touch patient" (Figure 5-3) and

– automatically begins charging.

You can watch the defibrillator charging. When the charge level has been reached,

– the device emits an audio signal

– the message "Energy available" appears,

– the charged energy will be displayed (Figure 5-3).

- Do not touch the patient any more and warn all those present.
- Now trigger the shock within 30 seconds. To do so, simultaneously press Charge Shock and Shock (Figure 5-4).

If the analysis algorithm does not detect a shockable rhythm, the message "No Shock Advised" is displayed and an audio signal sounds.

Note

- ***Activating the energy selector during ECG analysis will abort the analysis and you have to restart it.***
- ***ECG analysis takes 8 to 12 seconds. If you press the Analyse button immediately after delivery of a shock, this period may be extended to 20 seconds.***

Note

- ***Immediately after selecting "Autoseq", the charge sequence restarts with the lowest energy level. There is no time limit for the Autosequence shocks. The Autosequence can only be interrupted by activation of the energy selector.***
  The energy level selected for the 3rd shock is maintained for all subsequent shocks.
- ***If the shock is not delivered within 30 seconds of charging, an automatic internal safety discharge will be initiated. In this case you must press the Analyse button again.***

Note

If the analysis algorithm does not recommend a defibrillation, even though the patient is suspected to suffer from a shockable arrhythmia, press Analyse again. If possible, apply ECG electrodes to acquire the ECG.
Also the device can be switched to manual defibrillation by authorized personnel.

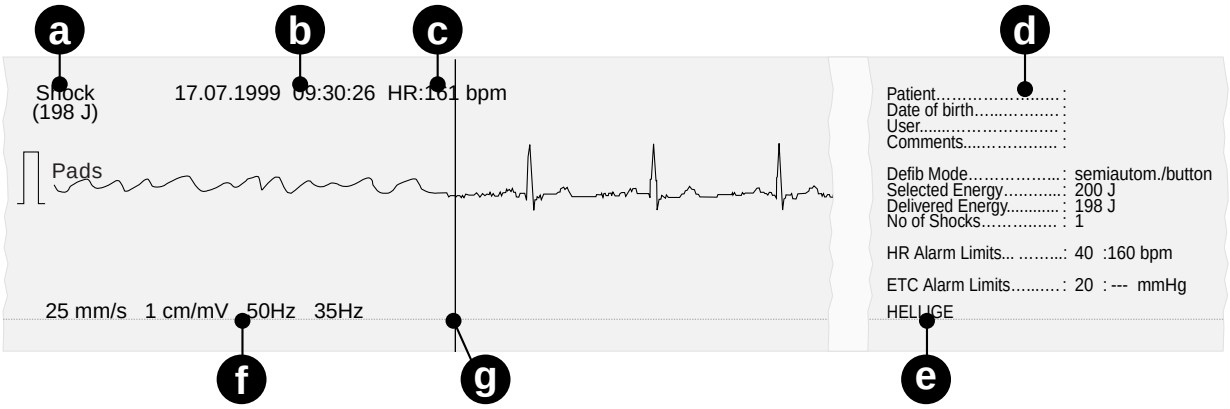


Figure 5-5. Example of a recording initiated by a defibrillation shock
a *reason for recording, delivered energy*
b *date, time*
c *heart rate*
d *intervention report*
e *user text*
f *speed, gain, filter(s)*
g *shock delivery, 5 seconds blanked*

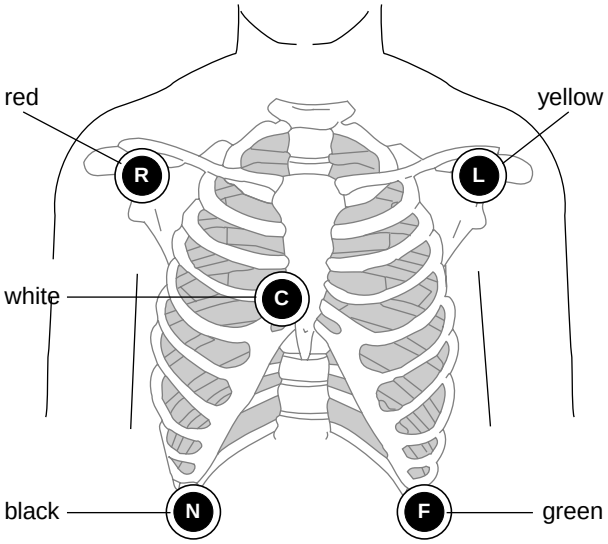


Figure 5-6. ECG electrode placement

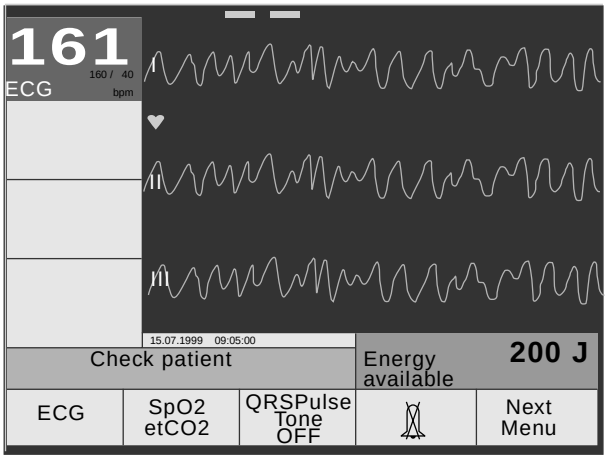


Figure 5-7. ECG display (acquisition via separate ECG electrodes)

Note

The main menu will automatically reappear, when no button is activated for a period of 30 seconds.

ECG Acquisition via Separate ECG Electrodes

Use only silver/silver-chloride electrodes to acquire the ECG signal. These electrodes prevent polarization voltages which may be caused by the defibrillation shock, resulting in an ECG trace on the monitor screen or recording that simulates cardiac arrest. The ECG can be picked up with 5 or with 10 electrodes (for ECG measurement, however, 10 ECG electrodes are required (chapter 8)).

- Apply the electrodes as shown in Figure 5-6.
- Ensure that only those leadwires are connected to the patient cable that are actually required.
- Via the patient cable, connect the electrodes to the defibrillator.
- Turn on the device (energy selector to).

On the monitor screen you will now see the 3 ECG leads selected in the setup menu (factory defaults: leads I, II, III, Figure 5-7). The analysis algorithm always uses ECG lead II. If lead II is not available, the first suitable ECG lead shown will be selected.

Follow these steps to change the displayed leads or the signal size:

– Press **F1** [ECG] .

– Press **F1** [I...III, aV...V, Paddle] again.
A menu for selection of the ECG lead appears.

– Using **F1**, select the lead to be displayed in channel 1, with **F2** select the lead for channel 2, and with **F3** select the lead for channel 3 (with each key press the device advances to the next lead).

– Press **F5** [Previous Menu] and change the signal size with **F2** [1 cm/mV].

– Press **F5** [Next Menu] for about 2 seconds to return to the main menu.

- Defibrillate the patient as described on page 32.

6 Pacemaker

Some Basic Facts

Application and Functional Description

The transcutaneous pacemaker of the Marquette Responder® 3000 is used for external (transchest) cardiac stimulation in emergencies. It is applied temporarily in cases of acute arrhythmia, such as cardiac arrest or Stokes-Adams attacks. Specific forms of bradycardia and tachycardia can also be treated with the pacemaker.

The pacemaker offers two modes of operation: demand and fixed-rate pacing ("Fix").

The pacer pulses are delivered via the adhesive defibrillation electrodes (pace pads). Electrodes 919 202 94 (for adults) and 919 202 09 (for children) can be used.

Separate ECG electrodes must be applied for acquisition of the ECG signal.

Warning

Shock Hazard — Due to their functional requirements, pacemakers operate with high voltages and are therefore equipped with specially protected outputs. Nevertheless, it is important not to touch live contacts with conductive metal objects, such as tweezers, as long as the pacemaker is operating. Currents exceeding 10 µA may induce ventricular fibrillation, if they flow through the heart. Observe the following sequence of operating steps when turning the pacemaker on and off:

Turning the pacemaker ON:

1. ***Apply ECG electrodes to patient.***
2. ***Connect ECG electrodes to the device.***
3. ***Turn on the Marquette Responder® 3000 (energy selector to).***
4. ***Check ECG and vital signs.***
5. ***Attach pace pads to patient.***
6. ***Connect pace pads to the Marquette Responder® 3000.***
7. ***Turn the pacemaker ON (button).***

Turning the pacemaker OFF:

1. ***Turn the pacemaker OFF (button).***
2. ***Disconnect pace pads from the Marquette Responder® 3000.***
3. ***Remove pace pads from patient.***
4. ***If monitoring of the patient is no longer required, turn off the Marquette Responder® 3000 (energy selector to OFF).***
5. ***Remove ECG electrodes from patient.***

Caution

Success of the Intervention — Verify the success of pacemaker stimulation by measuring the pulse rate, not the heart rate.

Warning

Pausing the Pacemaker — Pushing the button automatically pauses the pacer output and suspends delivery of pacer pulses. Pressing the button will terminate the pacer pause and resumes pacing with the previous settings.

Guidelines for the Application of External Pacemakers

All electrical devices that deliver energy to patients in any form or have an electrically conductive connection to the patient present a potential hazard.

The user is responsible for the safe application of the devices. Observance of the instructions given in the user manual and of the guidelines below is therefore of utmost importance:

- Pacemakers must only be used under the supervision of qualified and authorized staff.
- The prerequisite for safe application is the use of intact devices in rooms that meet the applicable requirements. Expert knowledge, good organization and special care in selecting the technical installation as well as regular maintenance are required to ensure such operating conditions.
- Medical electrical devices such as the Marquette Responder® 3000 must only be handled by persons who are trained in the use of such equipment and are capable of applying it properly.
- Before using the device, the operator is obliged to verify that it is in correct working order and operating condition.
- It is assumed that the patient's ECG is being monitored to be able to assess the effect of pacing. Furthermore, at least one of the persons present must be trained in the use of the defibrillator.
- Check the defibrillator performance before using the pacemaker on a patient.
- The pulse current output of the pacemaker is ungrounded. This ensures that the pacer current only flows between the pacemaker electrodes.
- If the patient needs to be defibrillated while the pacemaker is on, the pacemaker pauses when the defibrillator begins charging, and the delivery of pacer pulses is suspended. After delivery of the defibrillation shock, you can resume the pacemaker operation with the previous settings by pressing Start Pause.
- Use only the electrodes and cables listed in chapter 20 "Order Information".

Warning

Shock Hazard — During pacing set the energy selector to ***to prevent that a defibrillation pulse is triggered inadvertently.***

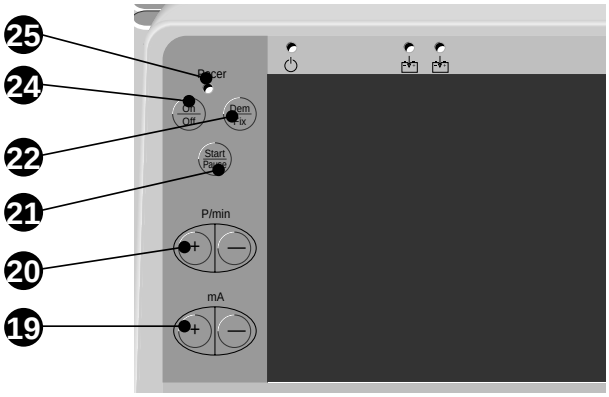


Figure 6-1. Pacemaker operating controls
***19** Button to change the pacer current output*
***20** Button to change the pacer rate*
***21** Button to pause the pacer function (settings remain stored)*
***22** Button to toggle between demand and fixed-rate pacing*
***24** Button to enable and disable the pacemaker*
***25** Indicator is illuminated when the pacemaker is on and goes off briefly with each delivered pacer pulse*

Demand Pacing

Caution: The pacer pulses are delivered via the adhesive defibrillation electrodes which must be applied as described in chapter 4.
Separate electrodes must be applied for acquisition of the ECG signal (chapter 7).

The pacemaker can be enabled only when adhesive electrodes are connected.

In demand mode, the pacemaker does not deliver pacing pulses as long as the patient's intrinsic heart rate exceeds the set pacing rate. When the heart rate drops below the pacing rate, the pacemaker starts emitting stimulation pulses. This can only be ensured by continued electronic monitoring of the ECG. The necessary synchronization pulses are automatically sent to the pacemaker.

The demand mode is the recommended pacing mode when the patient is at risk of developing bradycardia or even cardiac arrest as a result of a critical event. As the pacemaker function is controlled by the patient's ECG, the harmful competition between intrinsic and external stimulation which could induce ventricular fibrillation is excluded.

- Check that the ECG electrodes and the pace pads are correctly applied and connected to the device.
- Press On/Off (**24**, Figure 6-1) to turn on the pacemaker.

The device defaults to the Demand mode and selects a pacer rate of 60 P/min (configurable) (Figure 6-2).

Caution

Interrupted Arrhythmia Monitoring — Arrhythmia monitoring is disabled while the pacemaker is operating.

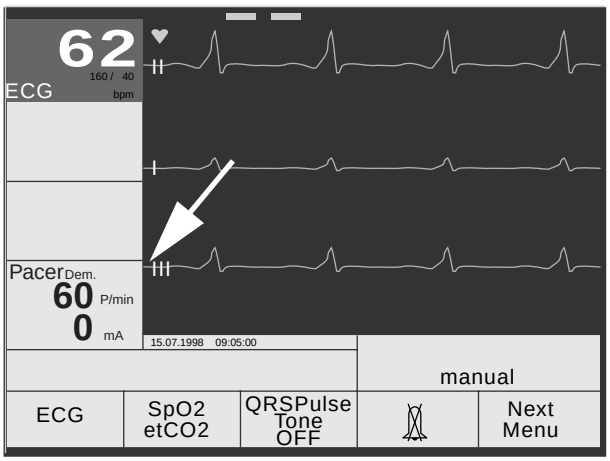


Figure 6-2. Pacer window

- Select a low pacer current output with mA, e.g. 20 mA (**19**, Figure 6-1).
- Select the required pacer rate with P/min.
- Now increase the pacer current output slowly with mA until the heart reliably responds to the stimulation.
- Increase the pacer current output another 5 mA to ensure continued stimulation.
- Verify the stimulation by watching the ECG on the display.
- You can press Start Pause to pause the stimulation and press Start Pause again to resume pacing with the same settings.
- After therapy, **turn off the pacemaker before removing the pace pads carefully.**
  (To turn off the pacemaker press the On Off button for at least 2 seconds (this is to prevent that the pacemaker is turned off inadvertently.) For this reason the Marquette Responder® 3000 cannot be turned off while the pacemaker is on.

Note

- ***The default pacer rate can be configured.***
- ***If a defibrillation shock is triggered during pacing, the pacemaker pauses automatically.***
- ***End the therapy as described under "Demand Pacing" above.***

Caution

Interrupted Arrhythmia Monitoring — Arrhythmia monitoring is disabled while the pacemaker is operating.

Fixed-Rate Pacing

Caution: The pacer pulses are delivered via the adhesive defibrillation electrodes which must be applied as described in chapter 4.
Separate electrodes must be applied for acquisition of the ECG signal (chapter 7).
The pacemaker can be enabled only when adhesive electrodes are connected.
In fixed-rate mode, the device delivers pacing pulses at the selected rate and current. The selected rate remains constant and is not affected by intrinsic actions of the patient's heart. This is the preferred mode for cases of cardiac arrest.

- Check that the ECG electrodes and the pace pads are correctly applied and connected to the device.
- Press On/Off (**24**, Figure 6-1) to turn on the pacemaker. The device defaults to the Demand mode and selects a pacer rate of 60 P/min (configurable).
- Press the Dem/Fix button for 3 seconds to activate the fixed-rate pacing mode (in the pacemaker window on the screen, you will see "Fix" instead of "Dem" (Figure 6-2).
- Indicator **25** (Figure 6-1) goes off briefly with each **delivered** pacing pulse.
- Select the required pacer rate with P/min +/−.
- Now increase the pacer current output slowly with mA +/− until the heart reliably responds to the stimulation.
- Verify the stimulation by watching the ECG on the display.
- Increase the pacer current output another 5 mA to ensure continued stimulation.

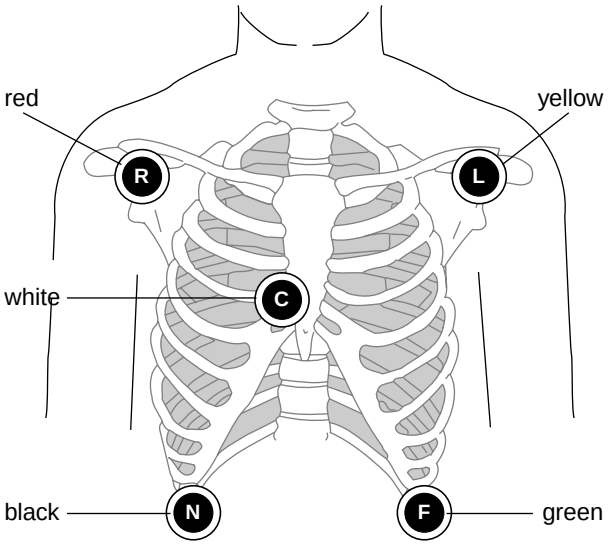


Figure 7-1. Signal acquisition with 5 electrodes

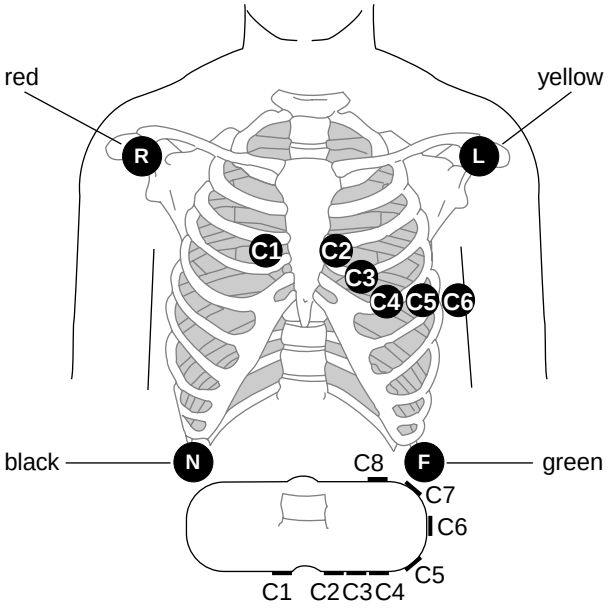


Figure 7-2. Chest electrode placement

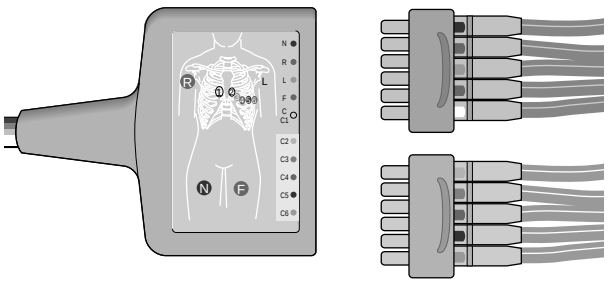


Figure 7-3. Connecting the leadwires to the patient cable

7 Displaying and Monitoring the ECG

Displaying the ECG

For a quick diagnosis of the ECG, you can use the defibrillation electrodes (paddles) to acquire the ECG.
For in-depth examinations and heart rate monitoring, the ECG signal should be acquired via separate ECG electrodes. Five or 10 ECG electrodes can be applied to the patient. Ten electrodes are required for the 12SL measurement and interpretation program. Use silver/silver chloride electrodes, if possible. Otherwise the polarization voltages caused by the defibrillation shock could simulate cardiac arrest.

- If you are using only 5 electrodes, apply them as shown in Figure 7-1. When working with 10 electrodes, additionally apply all chest electrodes as shown in Figure 7-2.
- Connect one (5 electrodes) or both leadwire blocks to the patient cable (Figure 7-3).

Ensure that all leadwires are always connected. Otherwise the connector of the leadwire may come in contact with conductive parts and cancel the protection provided by the isolated patient input.

- Set the energy selector to .

After the test screen, the standard screen display will appear (Figure 7-4), showing leads I, II and III (factory defaults).

Note

– ***ECG lead II is used for analysis and for calculation of the heart rate. If lead II is not available, the first suitable ECG lead displayed will be selected.***

– ***The 3-lead patient cable cannot be used with this defibrillator.***

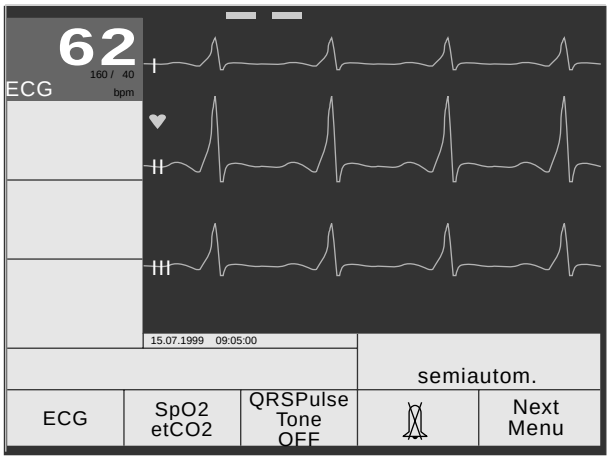


Figure 7-4. Standard screen display with ECG

Note

The main menu will automatically reappear, when no button is activated for a period of 30 seconds.

The HR window is green, indicating that no electrode problem was detected and the heart rate is within the alarm limits. If an electrode problem exists, the color changes from green to blue (in addition, an audio signal sounds after 30 seconds - configurable). If the HR violates one of the alarm limits, the color changes from green to red.

The default defibrillator settings are:

– leads I, II, III (configurable)

– AC line filter enabled, muscle filter enabled (configurable)

– gain 1 cm/mV (configurable)

– the audio alarm for heart rate and CO_2 monitoring is disabled

– arrhythmia monitoring is enabled (do not rely on this alarm alone because it will only be activated in the event of shockable arrhythmias; also monitor the patient by means of the HR alarm limits).

These settings can be changed permanently from the setup menu (chapter 13 "Defibrillator Setup") or temporarily.

For monitoring of the heart rate, please observe the information in the following section "Heart Rate Monitoring".

Assigning Channel Waveforms

- Press **F1** [ECG] .
- Press **F1** [I...III, aV...V, Paddle] again.
- Using **F1**, select the lead to be displayed in channel 1, with **F2** select the lead for channel 2, and with **F3** select the lead for channel 3 (with each key press the device advances to the next lead).

Gain Selection

- Press **F1** [ECG] .
- Change the signal size with **F2** [1 cm/mV].

Activating and Deactivating Filters

Activating muscle and AC line filters makes the displayed ECG insensitive to AC interference and muscle tremor. However, the filters alter the ECG signal, and a filtered signal is not suitable for diagnosis (displayed or printed ECG). The heart rate is always derived from the raw ECG signal.

- Press **F5** [Next Menu] .
- Using **F1** [Filter], enable or disable the muscle filter, as appropriate.
- The AC line filter is enabled and disabled from the setup menu.

> **Note**
>
> ***Active filters will alter the ECG signal. Switch off the filters to obtain a diagnostic ECG.***

Enabling/Disabling the QRS Beep

The QRS beep can be enabled (high, middle, low volume) and disabled with **F3** [QRSPulse Beep].

Warning

- ***No Asystole Alarm — The defibrillator gives asystole alarm only when the heart rate falls below the low HR limit. Therefore, do not disable the low HR limit.***
- ***Incorrect HR / No HR Alarm — In the presence of arrhythmias and morphological changes of the ECG, the device may not be able to calculate the correct heart rate. Beats may be counted twice or may be ignored.***

Note

- ***The defibrillator can be set up to automatically activate the alarm tone on power up. The default alarm limits can also be adjusted in the setup menu.***
- ***Furthermore the defibrillator can be set up for continuous ECG analysis. If the algorithm identifies shockable arrhythmias, the defibrillator will display the message "Check Patient" (manual defibrillator) or "Press Analyse" (semiautomatic defibrillator). When the audio alarms are active, the device will also emit an audible signal.***
  During patient transport the device may fail to identify these arrhythmias due to motion artifact.

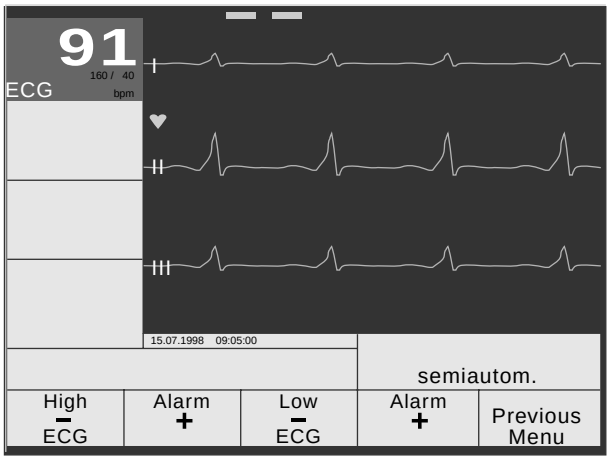


Figure 7-5. Buttons for modification of the HR alarm limits

Monitoring Heart Rate

The default heart limits are 40 and 160 bpm and the audio alarm is disabled (factory default settings, bell symbol in button **F4** is crossed out). The audio alarm can be enabled permanently from the setup menu or temporarily with **F4** (symbol appears).

The defibrillator reports an alarm condition if the HR exceeds one of the alarm limits for more than 10 seconds:

– the HR window and the QRS indicator change from green to red,

– the audio alarm sounds (configurable),

– the recorder starts (configurable),

– the alarm is annotated in the full disclosure ECG.

When the parameter reading returns to the normal range, the window and the QRS indicator change back to green and the audio alarm stops.

You can also silence the alarm tone with **F4** . If the alarm cause persists, the alarm condition is reported again after 120 s (a count-down timer in the button indicates the remaining time in seconds).
To permanently disable the audio alarm, press the button longer than 2 seconds. Then the symbol reappears.

The alarm limits can be modified permanently from the setup menu or temporarily as described below:

- Press **F1** [ECG] .
- Press **F3** [Alarm Limits] .

The display shown in Figure 7-5 will appear.

- Change the high limit with **F1/F2** and the low limit with **F3/F4.**

Monitoring Arrhythmia

The device allows you to continuously monitor the ECG for arrhythmias (see Appendix "The Arrhythmia Detection Program").

The program is enabled and disabled from the setup menu (see chapter 13, section "Device – Analysis").

When the program is active, you will see the message "VF/VT" in the ECG parameter window (Figure 7-6).

When the analysis algorithm detects a shockable arrhythmia, the message "Check Patient" (manual defibrillator) or "Press Analyse" (semiautomatic defibrillator) is displayed, and the device will also give VF alarm. When the audible alarm is active you will also hear an alarm tone.

Enabling the pacemaker will automatically interrupt the arrhythmia monitoring program.

Due to motion artifact the device may not be able to detect these arrhythmias during patient transport.

Note

Do not rely on this alarm alone because it will only be activated in the event of shockable arrhythmias; also monitor the patient by means of the HR alarm limits.

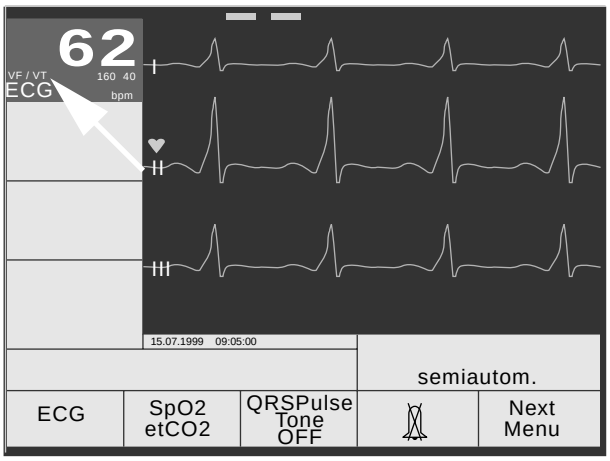


Figure 7-6. Arrhythmia monitoring enabled

Monitoring Pacemaker Patients

When monitoring the heart rate of pacemaker patients, only the patient's QRS complexes must be counted and pacer pulses must be rejected. For this purpose, the Marquette Responder® 3000 has an electronic pacer pulse suppression algorithm which rejects the pacer pulses so they are not counted as QRS complexes. Depending on the pacemaker model used and on the position of the electrodes, the compensation pulse following every pacer pulse may be considered as a QRS complex. Every pacemaker must provide an oppositely charged current (reverse current) after delivering a pacing pulse. In this situation and when the pacer pulse is ineffective, the displayed heart rate may be misinterpreted, and the device will not give alarm in the presence of bradycardia or asystole.

Always monitor pacemaker patients by means of separate ECG electrodes and not via the defibrillation electrodes.

As an additional precaution, monitor pacemaker patients by means of pulse oximetry.

It depends on the pacer pulse parameters, whether or not the compensation pulse is counted as a QRS complex (see chapter 19 "Technical Specifications").

For pacemaker patients, the ECG signal size should be greater than 1 mV.

Warning

No HR Alarm — If several adverse conditions exist at once during monitoring of pacemaker patients, the possibility that pacer pulses are interpreted (and counted) as QRS complexes should be considered. Therefore, pacemaker patients should always be watched closely.

8 12-Lead ECG Analysis Program (12SL ™)

Introduction

Overview

The first human electrocardiogram was taken over a hundred years ago, and computerized electrocardiography has been in existence since the late 1950s.

The pioneers of this technology had motivations which could mimic human activity to the basic requirement of efficiently recording artifact free tracings.

Computerization has resulted in two practical advantages for the overreading physician. First, the computer can serve as an additional expert opinion. Second, cardiologists have found that it is possible for them to overread computer analyzed tracings in half the time required for conventional, non-analyzed ECGs.

The computer, therefore, is not only used to efficiently record, store, transmit, and present the ECG; but it is also used to assist the physician in overreading an ECG.

It should be made clear that a computerized analysis is not a substitute for human interpretation. There are two reasons for this. *First, statements of accuracy need to be viewed from a statistical perspective. Although accuracy levels may be high, outliers can and will exist. Second, a computer does not have the ability to include the entire clinical picture of the patient.* A person with organic heart disease can exhibit an ECG within normal limits. Conversely, a normal individual can have an abnormal appearing ECG. The ECG, therefore, must always be reviewed in light of the surrounding clinical circumstances.

A program's accuracy is directly dependent upon the quality of the signal it acquires. In 1979, Marquette Hellige introduced an electrocardiograph that simultaneously acquired all of the leads from the 12-lead electrocardiogram. Prior to this time, all commercially available electrocardiographs could only acquire 3 leads at a time.

Simultaneous recording was adopted so that the computer could use all signals from all 12 leads to properly detect and classify each QRS complex.

Median Beat, Signal Averaging

Computer measurement for features within the QRS complex are very susceptible to artifact. To remove artifact, filtering may be used. Beyond filtering, there is another method able to eliminate noise from the QRS complex: signal averaging. Instead of analyzing a single QRS complex, the 12 SL program generates a median complex. In other words, all QRS complexes of the same shape are aligned in time. Next, the algorithm generates a representative QRS complex from the median voltages that are found at each successive sample time. This is more complicated than creating an average. The method results in a cleaner signal since it is able to disregard outliers.

Comparisons of all averaging against all non-averaging programs yields a 70% higher detection instability for the non-averaging programs and worse performance in most tested measurements.

Measurements, Onsets and Offsets

All ECG computer programs are composed of two parts: one which measures the waveforms and one which does the analysis based upon those measurements. The main task of computerized measurement determines the location of major reference points (onsets and offsets for P, QRS, and T waves).
Consistent with the signal processing portion of the program, the major wave onsets and offsets are delineated by an analysis of the slopes in all 12 simultaneous leads. That is, QRS duration is measured from the earliest onset in any lead to the latest deflection in any lead. Similarly, the QT interval is measured from the earliest detection of depolarization in any lead to the latest detection of repolarization in any lead.
After the onsets and offsets for P, QRS, and T complexes have been demarcated, the waves within each complex are then measured according to published standards. These amplitudes and durations result in a measurement matrix containing more than 1600 values. Measurements are then passed onto the criteria portion of the program so that it can generate an interpretation.

Literature
"Marquette Hellige 12SL™ ECG Analysis Program",
PN MO 1417 DE 0, English

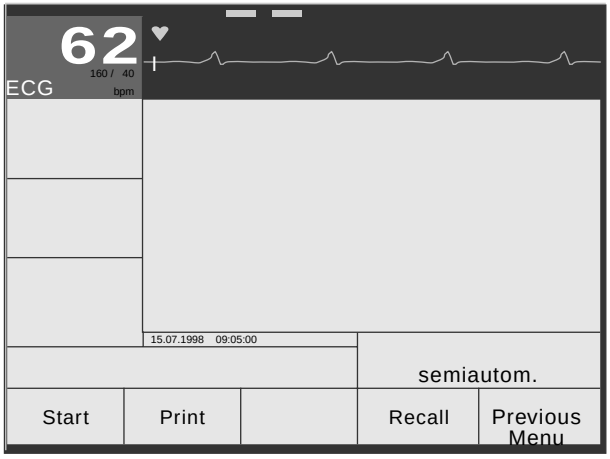


Figure 8-1. 12SL analysis menu

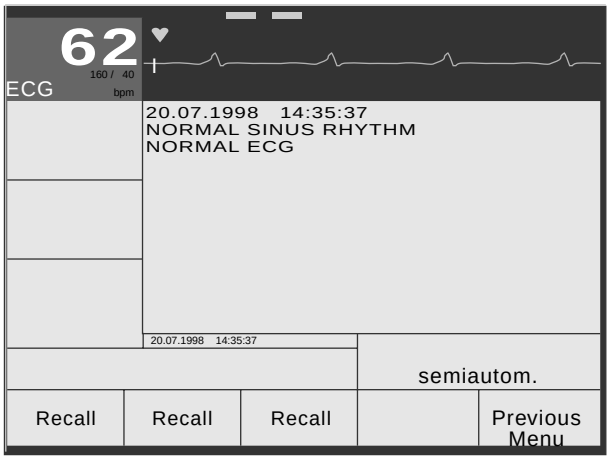


Figure 8-2. 12SL interpretation

12SL Measurement

For measurement and interpretation 12 seconds of ECG data are saved. After the analysis, the interpretation is presented on the monitor screen. You can also print the ECG including the measurement results and the interpretation. The printed segment, however, is only 3,2 seconds. If 12SL analysis was already performed with the defibrillator when you activate the program, the previous interpretation will appear on the display. In addition, the full-disclosure ECG of channel 1 is stored in the ECG memory.

- Press **F1** [ECG] .
- Display the 12SL menu with **F4** [12SL] (Figure 8-1).
- Press **F1** [Start] to start the program.

After acquisition, the ECG data is analyzed and stored. Afterwards, the interpretation is displayed on the screen (Figure 8-2).

Press **F2** [Print] to print the ECG, including measurement results and interpretation.

Press **F4** [Recall] to recall the 3 most recent 12SL records. The corresponding acquisition time is shown in the softkey.

9 Pulse Oximetry (SpO_2)

Some Basic Facts

SpO_2 measurement is used to determine the percentage of functional hemoglobin saturated with oxygen in the patient's arterial blood. Alarm limits can be set for monitoring of the SpO_2 value. The plethysmogram waveform can be displayed on the screen (Figure 9-1).

The device measures arterial oxygen saturation by a method called pulse oximetry. This method is based on the measurement of the different absorption spectra of reduced hemoglobin and oxyhemoglobin.

Therefore the probes consist of a light source (two LEDs in most cases) and a photodetector on the opposite side which collects the incident light. After interaction with the blood and tissue, the red and infrared light (range between 660 nm and 940 nm) from the LEDs hits the photodetector which converts it into an electrical signal. The pulsatile component of the signal is used to build the plethysmogram.

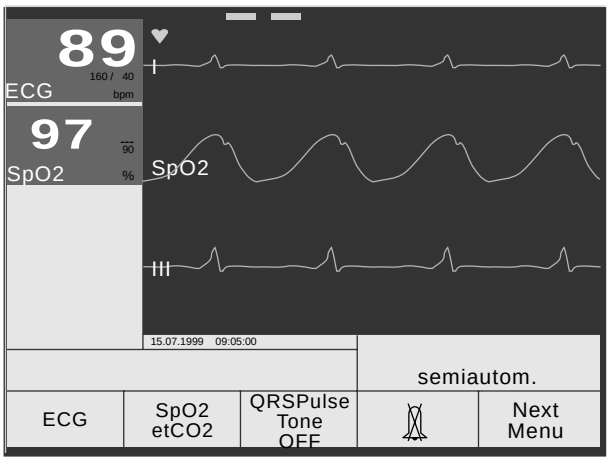


Figure 9-1. SpO_2 value and plethysmogram

Warning

False Parameter Readings — Pulse oximetry is not suitable for oxygen monitoring of fetuses (ante-partum or sub-partu). Also this method is not suitable for patients with carbon monoxide poisoning.
Elevated levels of carboxyhemoglobin (CO-Hb) and methemoglobin (Met-Hb) may affect the measured values. Also dyes injected in the blood stream (such as Cardiogreen) may impair measurement accuracy.

Warning

No Alarm — Under certain conditions the device may not be able to identify a signal disturbance when monitoring the patient. In this situation artifacts are capable of simulating a plausible parameter reading, so that the monitor fails to sound an alarm. In order to ensure reliable patient monitoring the proper application of the probe and the signal quality must be checked at regular intervals.

Literature

WUKITSCH, M.W.; PETTERSON, M.T.; TOBLER, D.R.;POLOGE, J.A.: Pulse Oximetry: Analysis of Theory, Technology, and Practice, J. Clin. Monit. **4**: 290–301 (1988)

CECIL, W.T.; THORPE, K.J.; FIBUCH E.E.; TUOHY, G.F.: A Clinical Evaluation of the Accuracy of the Nellcor N-100 and Ohmeda 3700 Pulse Oximeters, J. Clin. Monit. **4**: 31–36 (1988)

C-Lock ECG Synchronization

The C-Lock ECG synchronization feature enables the device to use an ECG signal as a reference point for identifying the pulse and synchronizing saturation measurements. This enhances the measurement accuracy when the patient's perfusion is poor and in the presence of patient movement.
When an ECG signal is present during SpO_2 measurement, the device receives two separate signals that reflect cardiac activity; an optical/electrical signal from the SpO_2 probe and the ECG signal. The time that elapses between the ECG R-wave and the optical pulse detected at the probe site depends on the heart rate and on the location of the probe. However, for a given patient the length of the delay is relatively stable, and the device uses that time relationship to identify good pulses and reject non-synchronized artifacts.

Application Tips

General Tips

- Use only the probes listed in chapter 20 "Order Information". Apply the probes as described in their instructions for use. Carefully observe all information and cautions given in these instructions.
- Take care that the probe does not exert too much pressure when applied to avoid erroneous readings and blistering. Inadequate oxygen supply to the skin, not heat, causes blisters.
- Change the probe site at least every 24 hours to allow the skin to breathe.
- Be careful to ensure continued circulation at the probe site.
- Incident light may cause inaccurate readings. Cover the measuring site with a cloth, if necessary.
- It may not be possible to measure SpO_2 values, if cardiac output is determined at the same time by means of the dye dilution technique.
- It may not be possible to measure SpO_2 values or the pulse rate, if the circulation is impaired (e.g. by a blood-pressure cuff or by an extremely high vascular resistance).
- Remove nail varnish and artificial finger nails before applying the probe. Both may lead to inaccurate readings.
- Do not apply the finger probe to the same arm as the blood-pressure cuff.

To minimize motion artifact

- take care to provide an ECG of good quality (C-Lock ECG synchronization),
- use a new probe with fresh adhesive backing,
- move the probe to a less active site,
- select a slow integration time.

When monitoring SpO_2 during electrosurgical intervention, take care that

- the device is powered from the internal battery or from a different power circuit than the electrosurgical unit,
- the ground pad is close to the surgical site,
- the probe is applied as far from the surgical site, the ground pad and the electrosurgical unit as possible.

In the presence of AC line interference

- When interference signals from the power line are present, square waves may be displayed instead of the plethysmogram. In this situation we recommend to disconnect the device from the power line and operate it on battery power.

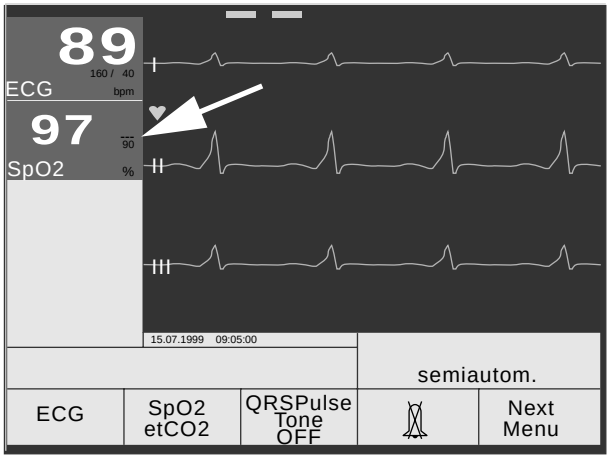


Figure 9-2. SpO_2 parameter window

Figure 9-3. SpO_2 menu

Note

Disable the C-Lock ECG synchronization feature when monitoring pacemaker patients.

Warning

Delayed Alarm — When monitoring the pulse rate derived from the SpO_2 signal instead of the heart rate, select an integration time of 4 or 8 seconds; do not select 12 seconds because of the slower display update.

Measuring and Monitoring Oxygen Saturation

- Apply the probe as described in the user instructions supplied with the probe and connect it to the defibrillator (blue connector).

The SpO_2 measurement begins as soon as the sensor is connected. During the short self-test, the parameter window is blue. As soon as the probe supplies a valid signal, the color changes to green (Figure 9-2).

At the factory, only a low limit of 90% is adjusted, no high limit. When the parameter reading drops below this value, the defibrillator sounds an alarm and the window changes from green to red.

Enabling/Disabling C-Lock ECG Synchronization

With the factory default settings unchanged, the C-Lock ECG synchronization is disabled when the device is first turned on. If the ECG signal is acquired, enable the feature.

- Press **F2** [SpO2 etCO2] .
- Press **F3** [SpO2] to display the SpO_2 menu (Figure 9-3) (displays only when SpO_2 probe is connected).
- Press **F1** [C-LOCK] to enable the C-Lock feature (or press the key again to disable it).

Selecting the Integration Time

The integration time is the time over which the measured values are averaged. You can select an integration time of 4, 8 or 12 seconds. The default setting is 8 seconds. The integration time of 12 seconds should only be selected in exceptional cases.

- Display the SpO_2 menu as described above (Figure 9-3).
- Select the integration time with **F2** [Integ. Time] .

Selecting the HR Source

The device can be set up to derive the heart rate from the SpO_2 signal. The heart rate source is selected with **F4** in the SpO_2 menu (Figure 9-3).

Adjusting Alarm Limits

The alarm limits can be modified permanently from the setup menu or temporarily as described below:

Figure 9-4. Alarm limits menu

Note

SpO_2 alarms are similar to HR alarms. Please refer to chapter 7 "Displaying and Monitoring the ECG".

- Press **F2** [SpO2 etCO2] .
- Press **F2** [SpO2 Alarm Limits] to display the alarm limits menu (Figure 9-4).
- Change the high limit with **F1**, **F2** and the low limit with **F3**, **F4**.
- To deactivate the SpO_2 measurement, remove the probe connector and press **F2** [SpO2 etCO2].

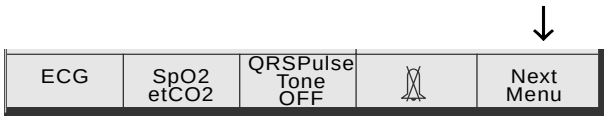


Figure 9-5. Main menu

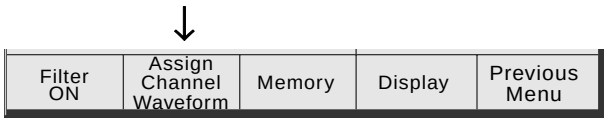


Figure 9-6. Main menu, page 2

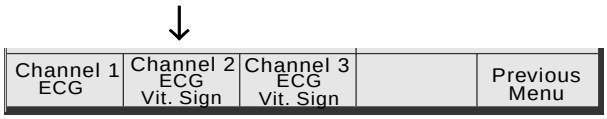


Figure 9-7. Menu to assign waveforms to channels

Displaying the Plethysmogram

The plethysmogram can be displayed in channel 2 or 3 with a sweep speed of 25 mm/s.

- Press **F5** [Next Menu] (Figure 9-5).
- Press **F2** [Assign Channel Waveform] (Figure 9-6).
- Press **F2** (Figure 9-7) repeatedly until "SpO_2" is displayed (Figure 9-8).
- When the SpO_2 measurement is disabled, a sawtooth signal is displayed which can be replaced with an ECG lead.

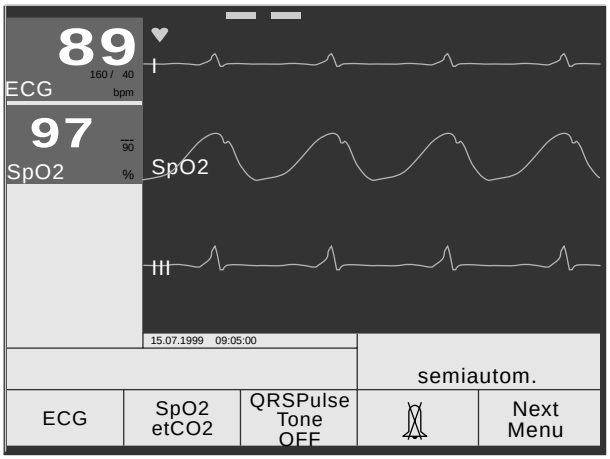


Figure 9-8. Plethysmogram in channel 2

10 Capnometry ($etCO_2$)

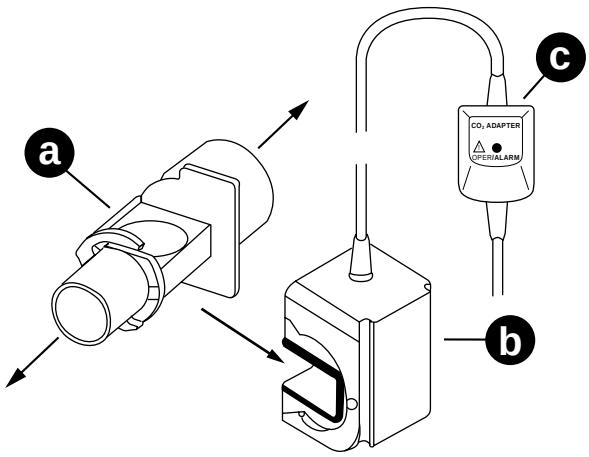


Figure 10-1. CO_2 sensor and airway adapter
***a** airway adapter*
***b** sensor*
***c** adapter cable*

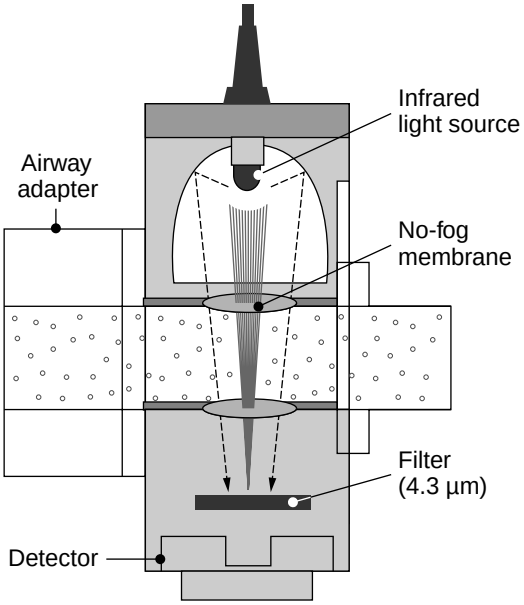


Figure 10-2. Principle of operation

Some Basic Facts

The $etCO_2$ sensor uses the infrared spectroscopy method. The sensor consists of the sensor itself **b** (including the IR source and the photodetector) and the airway adapter **a** which is attached to the sensor. The entire sensor is placed in the patient's airway (expired air) between the respirator and the tube. The airway adapter is for single use only. It must not be reused (Figure 10-1). The $etCO_2$ value is given in mmHg and can be monitored. A capnogram waveform can be displayed on the screen.

Principle of Operation

The method of infrared spectroscopy is based on the fact that the CO_2 gas in the patient's expired air absorbs infrared light at specific wavelengths. The absorbed amount of light is in proportion with the amount of CO_2 in the respired air. A "No-fog-membrane" ensures that no condensation collects on the sensor (Figure 10-2). The method used is a semi-quantitative measuring method and it is assumed that the inspired air is free of CO_2.

$etCO_2$ Monitoring Literature

Falk J L, Rackow E C, Weil M H (1988) End-tidal carbon dioxide concentration during cardiopulmonary resuscitation. New Engl J Med 318: 607-611

MacLeod B A, Heller M B, Gerard J et al. (1991) Verification of endotracheal tube placement with colorimetric end-tidal CO_2 detection. Ann Emerg Med 20: 267-270

Sanders A B, Kern K B, Otto C W (1998) End-tidal carbon dioxide monitoring during CPR: A prognostic indicator for survival. JAMA 262: 1347-1351

White R D, Asplin B R (1994) Out-of-hospital quantitative monitoring of end-tidal carbon dioxide pressure during CPR. Ann Emerg Med 23: 25-29

Bhavani-Shankar K; Mosley H; Kumar Y Y (1992) Capnometry and anaesthesia (Review Article). Can. J. Anaesth. 39: 617-632

Safety Information

Warning

Observe the following information to prevent erroneous CO_2 measurements. Inappropriate therapeutic measures based on erroneous readings may cause severe damage or the patient's death.

- ***$etCO_2$ measurement is not suitable for patients under 3 years of age or patients weighing less than 10 kg.***
- ***The sensor may give inaccurate readings when used on patients with a respiration rate greater than or equal to 60 breaths per minute.***
- ***$etCO_2$ measurement is not suitable for quantitative measurement during intraoperative anesthesia or in the ICU environment.***
- ***$etCO_2$ readings should be considered as additional parameters in the assessment of a patient's condition. They should always be seen in the context of other clinical signs and symptoms.***
- ***Do not use the sensor on patients with small tidal volumes because the dead space volume of the airway adapter is about 5 cc. This could affect the ventilation. If the tidal volume is too low, the sensor may not be able to detect the patient's inspiration and expiration.***
- ***Do not touch or wipe the window of the airway adapter to avoid damage. If the window is damaged, water droplets may adhere to the surface which could affect the performance and accuracy of the sensor.***
- ***The airway adapter can be continuously used for about 24 hours under normal operating conditions. If blood, sputum or phlegm has entered the airway adapter, discard the airway adapter and use a new one.***
- ***Do not measure the $etCO_2$ concentration on a patient undergoing an MRI examination. This could cause the sensor to give inaccurate readings.***
- ***High concentrations of nitrous oxide (N_2O) or halogenated anesthetic agents can cause the sensor to give inaccurate readings.***
- ***The sensor may give lower readings when used in a low pressure environment (do not use in airplane).***
- ***Do not allow condensation to develop in the sensor, condensation can attenuate the signal, resulting in degraded performance.***
- ***The sensor may give erroneous readings when exposed to rapid temperature changes.***
- ***The readings may be inaccurate when CO_2 is present in the airway adapter during inspiration. The displayed $etCO_2$ values are based on the assumption that the inspired air is free of CO_2.***
  The readings obtained during mouth-to-mouth resuscitation may therefore be inaccurate. The same is true if Jackson-Rees and Mapleson-D ventilators are used.
- ***The readings may be inaccurate in patients with high or irregular respiration rate (indicator in sensor goes briefly off).***
- ***The measurement accuracy depends on the altitude of the measurement site. It decreases with increasing altitude (Figure 10-6).***

Note

In most cases the endtidal CO_2 value ($etCO_2$) is below the arterial CO_2 partial pressure ($paCO_2$) determined by blood-gas analysis (see Literature). Possible clinical causes are:
- dead-space ventilation, ventilation/perfusion mismatch
- decreased cardiac output
- alveolar shunts
- incomplete emptying of the alveoli.

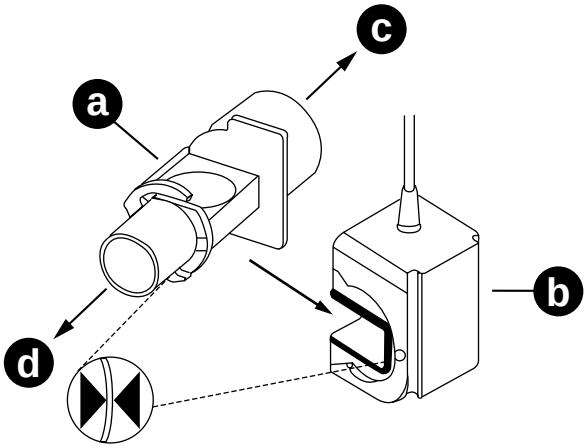


Figure 10-3. Attaching the airway adapter

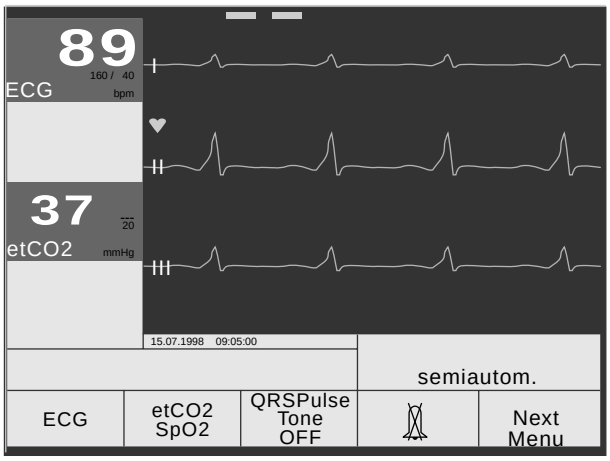


Figure 10-4. $etCO_2$ reading

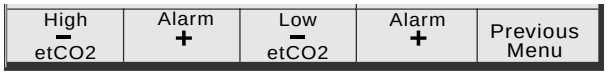


Figure 10-5. Alarm limits menu

Note

$etCO_2$ alarms are similar to HR alarms. Please refer to chapter 7 "Displaying and Monitoring the ECG".

Measuring and Monitoring $etCO_2$

- Obtain a new airway adapter and check that the windows are intact and clean.
- Attach the airway adapter to the sensor (the triangles on the airway adapter and on the sensor must be in alignment - Figure 10-3).
- Connect the airway adapter to the respirator system (connector **c** towards the patient, connector **d** towards the respirator - Figure 10-3).
- Ensure that the sensor is on top and that the windows of the airway adapter are in a vertical position. Although the "No-fog-membrane" prevents moisture condensation on the window, liquid secretions could soil the window.
- Connect the sensor to the defibrillator (yellow connector, right).

The CO_2 measurement begins as soon as the sensor is connected. During the short self-test, the parameter window is blue. As soon as the sensor supplies a valid reading, the color changes to green. Check that the indicator on the CO_2 adapter cable lights green; if a problem is detected, the indicator flashes red (apnea or system failure).

At the factory, only a low $etCO_2$ limit of 20 mmHg is adjusted, no high limit. When the parameter reading drops below this value, the defibrillator sounds an alarm and the window changes from green to red.

Adjusting Alarm Limits

The alarm limits can be modified permanently from the setup menu or temporarily as described below:

- Press **F2** [SpO2 etCO2] .
- Press **F1** [etCO2 Alarm Limits] to display the alarm limits menu (Figure 10-5).
- Change the high limit with **F1**, **F2** and the low limit with **F3**, **F4**.
- To deactivate the $etCO_2$ measurement, remove the sensor connector and press **F2** [SpO2 etCO2].

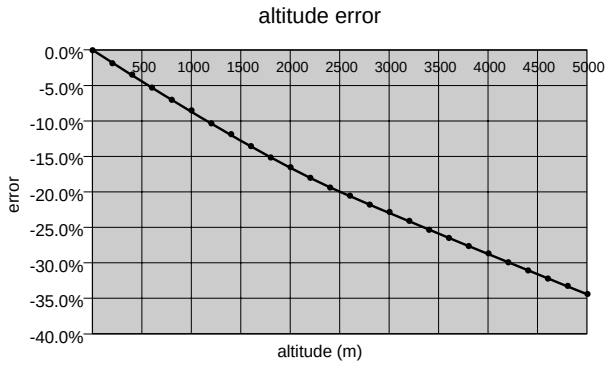


Figure 10-6. Measurement accuracy as a function of the altitude of the measuring site

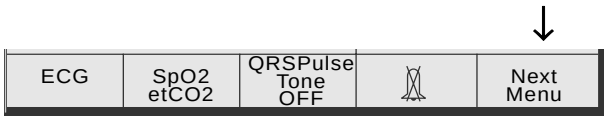


Figure 10-7. Main menu

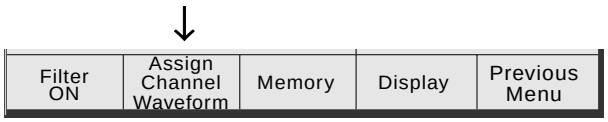


Figure 10-8. Main menu, page 2

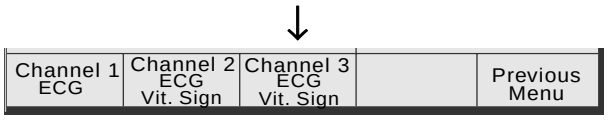


Figure 10-9. Menu to assign waveforms to channels

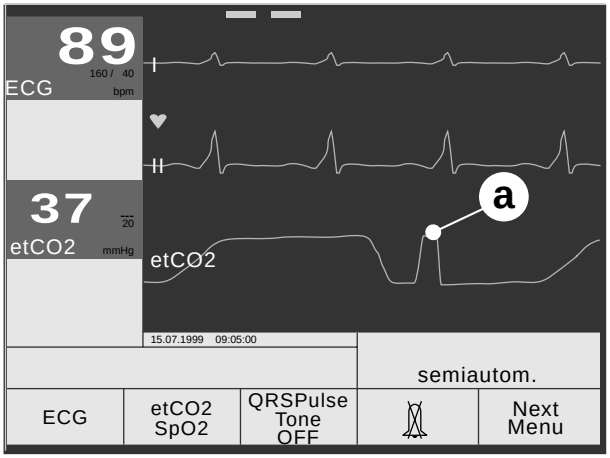


Figure 10-10. Capnogram in channel 3
***a** automatic sensor calibration*

Displaying the Capnogram

The capnogram can be displayed in channel 3 with a sweep speed of 6.25 mm/s (but it is printed with a speed of 25 mm/s).

- Press **F5** **Next Menu** (Figure 10-7).
- Press **F2** **Assign Channel Waveform** (Figure 10-8).
- Press **F3** (Figure 10-9) repeatedly until "$etCO_2$" is displayed (Figure 10-10).
- When the $etCO_2$ measurement is disabled, a sawtooth signal is displayed which can be replaced with an ECG lead.
- During the automatic sensor calibration process, a calibration pulse is superimposed on the capnogram (**a**, Figure 10-10).

Cleaning the Sensor

Use a soft cloth moistened with an alcoholic, non-abrasive cleaning agent to wipe the sensor surface including the IR light source, the photodetector and the connecting lead carefully clean. Use an alcoholic, non-abrasive cleaning agent.

Caution

Damage to Sensor — Do not use caustic or abrasive cleaners or hard cleaning utensils.

Do not touch the surface of the IR light source or of the photodetector with fingers or any hard object. This could affect the performance of these fine optical devices.

Do not autoclave the sensor or sterilize it with ethylene oxide.

Do not immerse the sensor in liquid.

Warning

Infection Hazard — The airway adapter is for single use only and must not be reused.

11 Memories of the Marquette Responder® 3000

Note

Switching off the defibrillator does not automatically clear the memories. Therefore, the memories could contain data from different patients.
We recommend to clear the memories before using the defibrillator on a new patient, or to program an event text "New patient" (see section "Event Button" in chapter 3 and "Event Texts" in chapter 13).
Changing the date and/or time will clear the memories.

The Marquette Responder® 3000 has 4 different memories:

– an event memory
– an ECG memory
– a trend memory
– a 12SL memory (optional).

Event Memory

The event memory stores up to 250 events, annotated with date, time and parameter readings (e.g. HR), which document the operating procedures (e.g. device on, off, alarms, defibrillation shocks, events - Event -).
When the event memory is full, the device updates the information automatically by saving new events and deleting old ones. It is also possible to clear the memories (see below).

When printing the contents of the memories you can choose between a list of the major events ("Primary Events") and of all events ("All Events").
The primary events include device on, device off, shock advised, no shock advised, pacer pause, configuration change, alarm silence and all alarms.

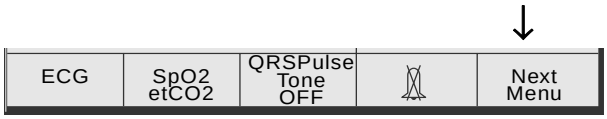


Figure 11-1. Main menu

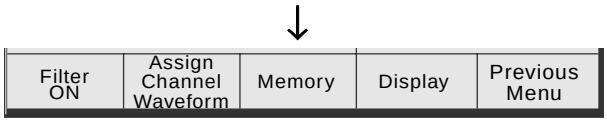


Figure 11-2. Main menu, page 2

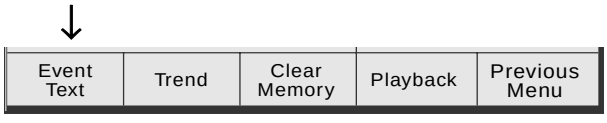


Figure 11-3. Memory menu

Figure 11-4. Memory menu

- In the main menu, select **F5** [Next Menu] (Figure 11-1).

You will see page 2 of the main menu (Figure 11-2).

- Press **F3** [Memory] (Figure 11-2).

You will see the memory menu (Figure 11-3).

- Press **F1** [Event Text].

You will see the menu shown in Figure 11-4.

- Press **F1** [Print Primary Events] to print the major events, or press **F2** [Print All Events] to print all events.

ECG Memory

The defibrillator saves the most recent 180 minutes of full disclosure ECG data displayed in channel 1 and acquired while the defibrillator was on. When the memory is full, the information is automatically updated, so that the most recent 180 minutes are always available. It takes about 1 minute before the stored ECG can be played back.

You can either print the full disclosure ECG in 5-second segments, or you can search the data for events that occurred in the last 180 minutes and then print the corresponding ECG strip.

Events whose ECG strips are older than 180 minutes are still listed in the event memory (if they are among the most recent 250 events), but the ECG strip is no longer available. When you attempt to print this event, the message "No ECG Data" will be displayed.

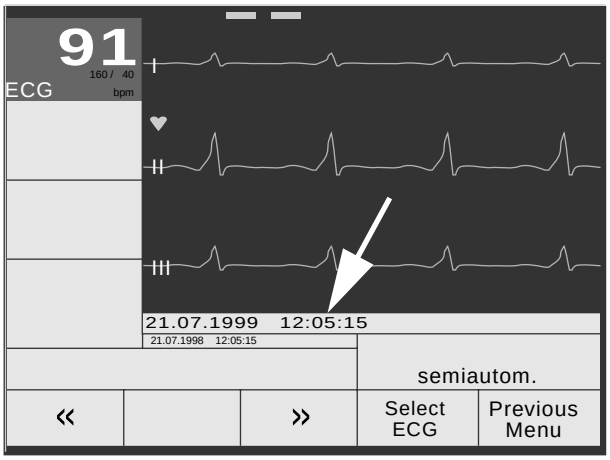


Figure 11-5. Playback function

Printing the ECG

- Press **F5** [Next Menu] in the main menu to display page 2 (Figure 11-2).
- Display the memory menu with **F3** [Memory] (Figure 11-3).
- Display the playback menu with **F4** [Playback] (Figure 11-5).

Now you can scroll through the stored ECG in steps of 5 seconds with **F1** and **F3**. The corresponding time is annotated below the waveform window (Figure 11-5).

- Press Print to print the displayed segment (press Print again to stop the printout).

If you want to find events in the full disclosure ECG, activate the search function with **F4** "Select Event". You can now move between events with **F1** and **F3**. Date and time of the event are displayed below the waveform window.

- Press Print to obtain a printout of the event.

Note

Power on and off are marked with a vertical line in the graphic trends.

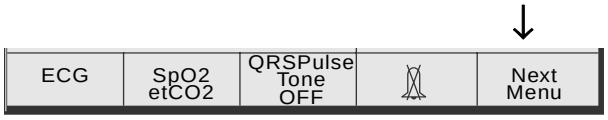


Figure 11-6. Main menu

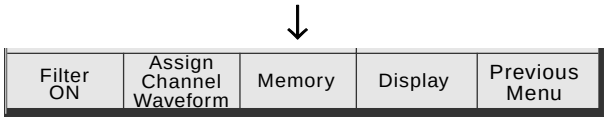


Figure 11-7. Main menu, page 2

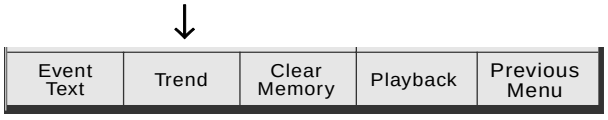


Figure 11-8. Memory menu

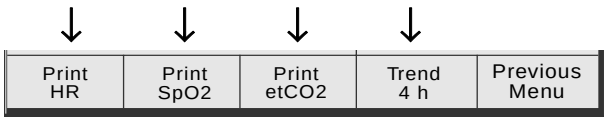


Figure 11-9. Trend menu

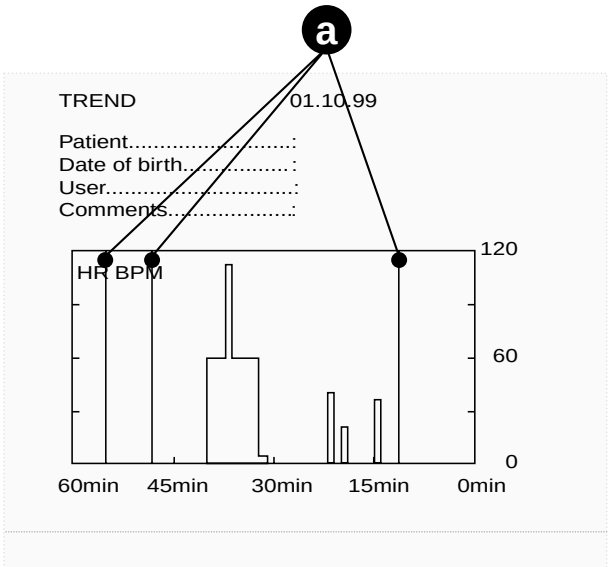


Figure 11-10. Graphic trend
***a** device OFF*

Trend Memory

In the trend memory the device collects the HR, SpO_2 and $etCO_2$ values of the past 4 hours. The trend data, too, are automatically updated. The stored data can be printed out in the form of graphic trends. You can choose between a 1-hour and a 4-hour trend window.

- Press **F5** [Next Menu] in the main menu to display page 2 (Figure 11-7).
- Display the memory menu with **F3** [Memory] (Figure 11-8).
- Display the trend menu with **F2** [Trend] (Figure 11-9).
- In the trend menu (Figure 11-9), select the time window [Trend 4 h] or [Trend 1 h] with **F4**.
- The following graphic trends are now available for printing:
  - heart rate with **F1** [Print HR],
  - SpO_2 with **F2** [Print SpO2],
  - $etCO_2$ with **F3** [Print etCO2].

Clearing the Memories

The memories cannot be cleared individually, all of them are cleared in one pass .

- Press **F5** [Next Menu] in the main menu to display page 2 (Figure 11-7).
- Display the memory menu with **F3** [Memory].
- Clear the memories with **F3** [Clear Memory]. Keep the button depressed until the text disappears.

12 Recording

Initiating a Recording

The recorder can be started and stopped with Print. With the factory settings unchanged, the recorder will print a 14-second strip of the displayed ECG and a status report when you press Print. Then the recorder stops. The recording can be stopped at any time with Print.

You can also set up the recorder to continue printing the ECG until stopped with Print (Cont. printout - ON).

Simultaneously press Print and Event.to obtain a hardcopy of the screen display.

Print Menu

- Press Print for approx. 2 seconds to display the print menu.

The display shown in Figure 12-1 will appear.

Figure 12-1. Print menu

- With **F1** [Contin. Printout] you can start and stop a continuous recording.
- With **F2** [Hardcopy] you can print a hardcopy of the screen display.
- With **F3** [14 s] you can print a 14-second ECG strip.
- With **F4** [Auto. Printout] you initiate an automatic (synchronized) recording of all leads (12 standard leads with 10-lead patient cable or 7 leads with 5-lead patient cable) (only in conjunction with the optional "12 SL" program).

In the setup menu, you can choose the condition for an automatic 14-second ECG strip (incl. a history of 4 seconds):

– upon delivery of a defibrillation shock ("Print on shock - ON")
– upon violation of a HR limit ("Print on alarm - ON").

On the recording, a dashed line marks the time the alarm/event occurred.

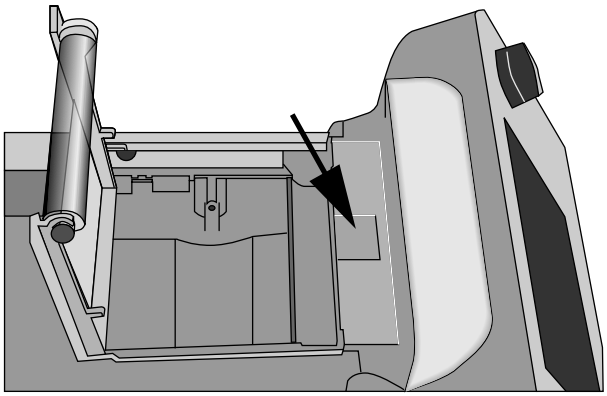


Figure 12-2. Opening the paper compartment door

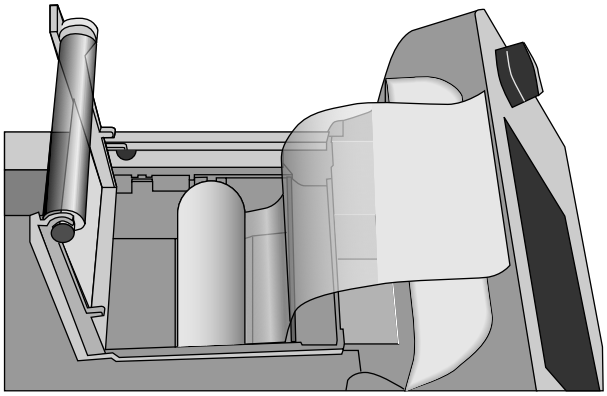


Figure 12-3. Inserting the new roll

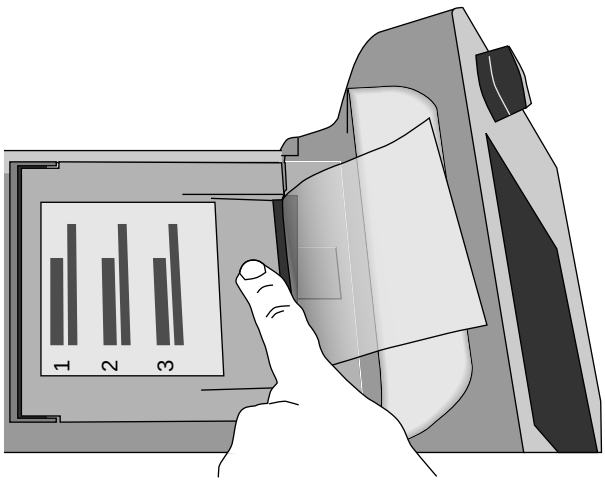


Figure 12-4. Closing the paper compartment door

Note

If you store the recordings in plastic folders these should be made of polyethylene, because the traces fade in PVC covers (if in doubt, insert a sheet of paper between recording and folder).

Loading Chart Paper

To prevent damage to the printhead, use the original HELLIGE CONTRAST paper only (P/N 226 168 02).

- Open the paper compartment door all the way (Figure 12-2).
- Remove the spindle with the sleeve of the previous paper roll.
- Insert the spindle in the new roll and place the roll into the device as shown in Figure 12-3.
- Pull a length of paper (approx. 15 cm) from the compartment and close the door (Figure 12-4). The paper compartment door must click into place audibly on both sides.

The last 3 meters of the roll paper are marked. Insert a new paper roll in time to ensure that all alarm recordings are documented.

Caution

- ***Risk of Skin Burns — When inserting a new paper roll, be careful not to touch the thermal printhead. Particularly after long recordings it may be very hot.***
- ***Paper Jam — When operating the defibrillator in the carrying bag, the flap covering the recorder must be open and secured with the Velcro fastener against dropping to prevent that it obstructs the paper exit.***

13 Defibrillator Setup

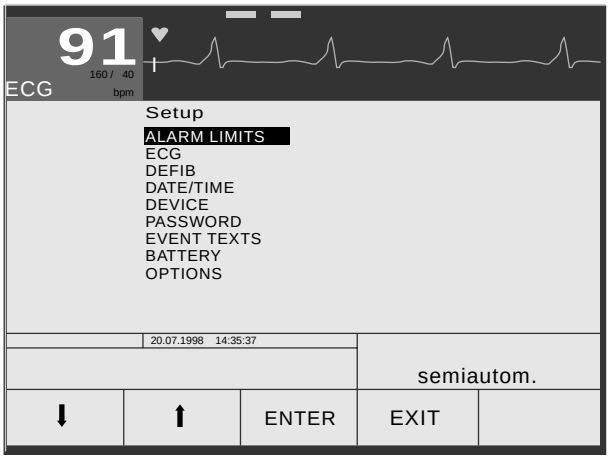


Figure 13-1. Setup menu

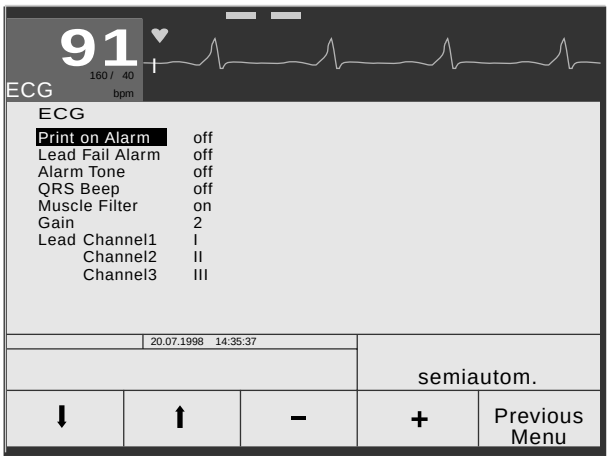


Figure 13-2. Setup, ECG menu

The defibrillator has a setup menu which allows you to adjust many of the device functions to your preferred settings and to save these as defaults which are activated each time the defibrillator is switched on.

Simultaneously press **F1** and **F5** to display the configuration menu (if the password function is enabled, you will be prompted to enter the password – see "Password" below).

You will see the setup menu as shown in Figure 13-1.

For a complete list of the parameters of each menu item, please refer to table 1 on page 15.

The operating steps are always the same:

- Use the arrow keys **F1**, **F2** to position the bar cursor on one of the topics and press [ENTER].

This will open the corresponding submenu, e.g. the ECG menu (Figure 13-2).

- Use the arrow keys to position the bar cursor on the parameter to change.
- Change the setting with **F3** [-] or **F4** [+] .
- Select [Previous Menu] to close the submenu.
- Select [Save & EXIT] to quit the menu and save the new settings.
- Select [EXIT] if you wish to quit the menu **without** saving the changes.

Alarm Limits
selection of the HR, SpO_2 and $etCO_2$ alarm limits

ECG
Print on Alarm
recorder starts upon violation of an alarm limit

Lead Fail Alarm
audio signal when electrode is off the patient

Alarm Tone
audio signal upon violation of alarm limit

QRS Beep
audio signal to the rhythm of the heart beat

Muscle Filter
elimination of motion artifact (35 Hz ECG, 20 Hz Paddles)

Gain
for the displayed ECG (0.5, 1, 2 cm/mV)

Lead Channel 1/2/3/Vital Signs
ECG leads and vital signs waveforms to display in the 3 channels, from top to bottom

Note

ECG lead II is used for analysis and for calculation of the heart rate. If lead II is not available, the first suitable ECG lead displayed will be selected.

Defib
Print on shock
recorder starts upon shock release

Operating Mode
semiautomatic, manual, semiautomatic/button, semiautomatic/password

When choosing "semiautomatic/password", the defibrillator requests a 3-digit password which can be entered with **F1**, **F2** and **F3** (factory-set password: "111").

Autosequence
entry of the energy levels for the 1st, 2nd and 3rd defibrillation shock

Pacemaker

default pacer rate

Date/Time
Date format
either DD.MM.YYYY (day, month, year) or MM/DD/YYYY (month, day, year).

Note

Date and time are saved immediately, without pressing Save & EXIT. All memories will be cleared.

Device
Display
screen display
normal, reverse, SmartFlip (automatic display flip after insertion in vehicle mounting unit)

Volume
for alarms, QRS beep, and alerts

Cont. Printout
Continuous printout enabled: When initiated with Print the recorder continues printing until stopped with Print .

Continuous printout disabled: When initiated with Print the recorder prints a 14-s ECG strip and then stops automatically.

Analysis
Enables/disables the arrhythmia monitoring program. When the analysis algorithm detects a shockable arrhythmia, the message "Check Patient" or "Press Analyse" will be displayed.

AC Line Filter
eliminates AC interference (50 Hz = filter enabled, 50 Hz AC line frequency in Europe; 60 Hz = filter enabled, 60 Hz AC line frequency in the USA)

Language
language selection for the display and recorder.

Factory Default
to restore the factory defaults
Restoring the factory defaults will not affect the device settings marked with the asterisks ** in table 1 on page 15.

User
entry of a text or of the institution name (will be printed in the lower margin of the recording strip) Using [←] or [→], choose the position for the character; with [↑] or [↓], choose the letter or number.

Password

The password function allows you to protect conversion of the defibrillator to the manual mode (for defib set up for "semiautomatic / password). With the same password you can also lock the setup menu, so that only persons knowing the password have access to this menu.

The factory-set password is 111, and access to the setup menu is not locked ("For setup - OFF").

To protect the defibrillator setup, choose "For setup - ON". In this case, you will have to enter the code combination before you can display the setup menu.

Changing the Password

- Using **F1** [↓] or **F2** [↑], position the bar cursor on PASSWORD and confirm the selection with **F3** [ENTER].

The password menu will be displayed. The bar cursor highlights the menu item "Password".

- Confirm the command with **F4** [+] .

The menu for entry of the password will be displayed.

0	0	0		ENTER

Figure 13-3

- First, enter the old password with **F1**, **F2** and **F3** (factory-set password: 111) and confirm it with **F5** [ENTER].
  If you do not remember your own password, you can use the master password (see footnote).

The menu for entry of the password appears only if you enter the current password at this point.

- Press **F2** [→] twice to display the current password (***).

←	→	↓	↑	ENTER

Figure 13-4

- Using the 4 cursor keys **F1**, **F2**, **F3** and **F4**, overwrite the current password with your new password and confirm it with **F5** [ENTER] .

The submenu appears.

↓	↑	–	+	Previous Menu

Figure 13-5

- Select **F5** [Previous Menu] to close the submenu.
- Exit the setup menu with **F5** [Save & EXIT] (or with **F4** [EXIT] , if you do not want to use the new password)**.**

✂----------

The master password which overrides all other passwords is 360 (can be used if you forget your own password).

Event Texts

Entry of up to 8 event texts (max. 8 characters each); these texts are assigned to the softkeys **F1** to **F4** (chapter 3, section "Event Button")
Using [←] or [→], choose the position for the character; with [↑] or [↓], choose the letter or number.

Battery

For details on the battery maintenance program, please refer to chapter 14, section "Battery Maintenance Program".

Options

For activation of optional program modules (Figure 13-6).
The defibrillator serial number has already been entered. We need to know this number when you order optional program modules. Then you will be given the option code number. When you enter this number and exit the configuration menu with [Save & EXIT] , the defibrillator will automatically restart and activate the new program module(s).

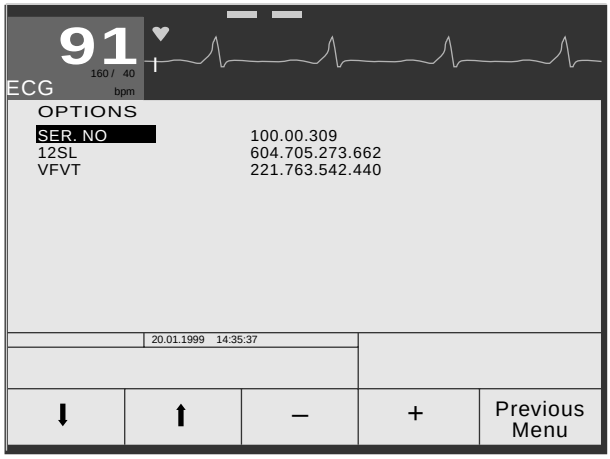


Figure 13-6. Activating optional program modules
12SL: ECG analysis program
VFVT: semiautomatic defibrillator

14 Battery Power Operation

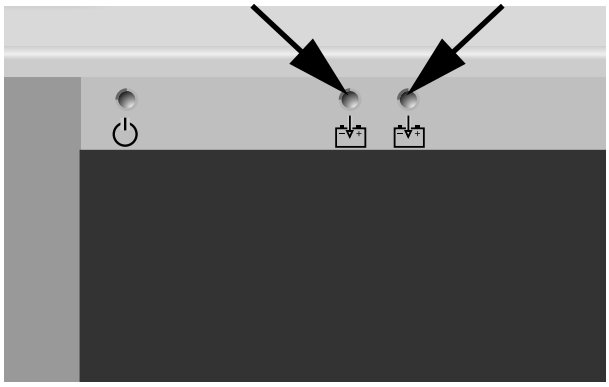


Figure 14-1. Battery charging indicators

Warning

- ***Operational Readiness — Defibrillators are emergency medical devices designed to save and preserve lives. They must be ready for use at all times. This applies also to mains-independent operation. Ensure that the device battery is always fully charged.***
- ***Do not recharge NiCd batteries in direct sunlight, on sources of heat or at extremely low ambient temperatures (minimum temperature 5 °C/41 °F). The ambient temperature should not exceed 40 °C/104 °F, as this could have adverse effects on the battery's service life.***

Battery Charging (ambulance power supply, power line)

The batteries recharge when you

– place the defibrillator in the vehicle mounting unit / wall mount unit or

– connect the defibrillator to the power line (units with AC power adapter).

The two indicators (Figure 14-1) light up when the batteries are charging. Charging will take approx. 4 hours per battery (the batteries are recharged one after the other). The defibrillator can be operated in the vehicle mounting system or on mains power, even when the batteries are discharged. Also observe the information given in chapter 16 "Operation in the Vehicle Mounting Unit".

Charging the Batteries with the Separate Charging Unit ASU 3000

In addition to charging the batteries, the charging unit also maintains them (see section "Information on Battery Power Operation" below). Please note the instructions given in the charging unit operator's manual.

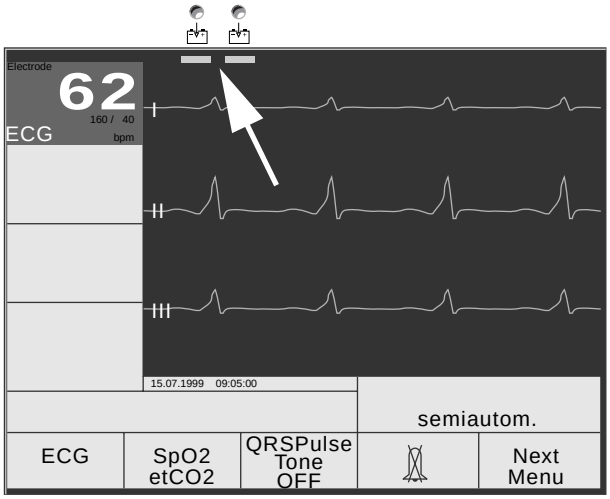


Figure 14-2. Battery charge level indicators

Note

The battery on the left is the working battery, the one on the right the spare battery. Exchange the batteries on a monthly basis.

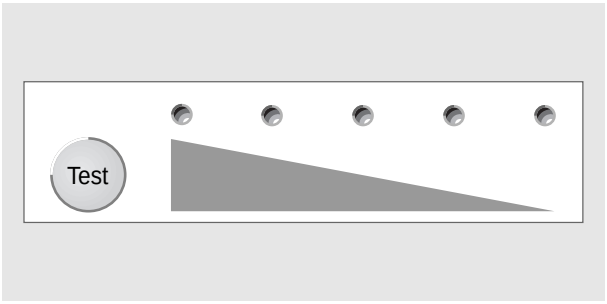


Figure 14-3. Battery test button and charge indicators

Information on Battery Power Operation

Rechargeable batteries require special maintenance and continued checks to assure they function in emergency situations. It is normal for batteries of this type to self-discharge, even when the device is switched off. Furthermore, the capacity decreases with age.
By regular maintenance (charging and discharging at regular intervals) the battery service life can be considerably extended. The defibrillator as well as the separate charging unit ASU 3000 have a special battery maintenance program (see next section).

To ensure that the Marquette Responder® 3000 will always function in an emergency, it must not be disconnected from an external power source for more than 48 hours (mains or ambulance power supply). Reconnect the defibrillator to the external power source immediately after use or recharge the batteries with the separate charging unit. The batteries cannot be overcharged.

The two horizontal bars in the upper margin of the screen (Figure 14-2) continuously indicate the battery charge level:

green: battery full (40 to 100%)

yellow: medium charge level (20 to 40%)

red: battery depleted (0 to 20%)

If two batteries are inserted, they will be discharged one after the other, not at the same time.

The battery charge level can be checked by pressing the **Test** button (Figure 14-3) on the battery (for this test, the battery does not have to be inserted in the defibrillator).

5 LEDs: charge level between 80 and 100%

4 LEDs: charge level between 60 and 80%

3 LEDs: charge level between 40 and 60%

2 LEDs: charge level between 20 and 40%

1 LED: charge level between 0 and 20%

no LED: battery depleted

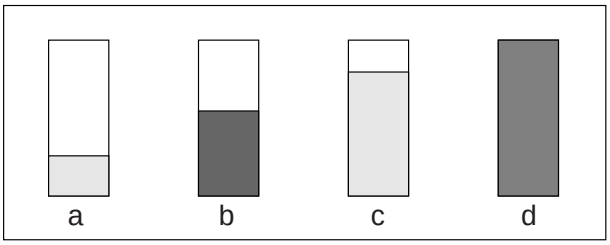


Figure 14-4. Battery maintenance indicators
a = yellow, battery charging
b = red, battery discharging
c = yellow, battery charging
d = green, battery charged

Note

- ***The waveform and trend memories are overwritten during the battery maintenance program.***
- ***At the end of the maintenance program, you can check the event memory for details of the battery maintenance routine.***

Warning

Operational Readiness — Recondition the batteries at least once every month. using either the separate charging unit ASU 3000 or the battery maintenance program.

Battery Maintenance Program

The batteries should be reconditioned once a month with the battery maintenance program. As the battery will be discharged in the course of the maintenance program, a second battery is required to ensure that the defibrillator is ready for use. The maintenance program can be activated with the defibrillator connected to the power line or to the ambulance power system.

- Connect the device to the power supply system.
- Turn on the defibrillator with the energy selector (position).
- Simultaneously press **F1** and **F5** to display the setup menu.
- Press **F1** to position the bar cursor on BATTERY and confirm the selection with **F3** ENTER.
- Press **F4** + to select the "Battery Maintenance ON" option and confirm the selection with **F5** Previous Menu .
- Set the energy selector to "Off".

This is what happens during the automatic maintenance program:

1. Battery 1 charges
2. Battery 2 charges
3. Battery 1 is discharged and then recharged
4. Battery 2 is discharged and then recharged
5. defibrillator prints maintenance report, then switches off (screen blanks)

The progress bar on the monitor indicates the battery status (Figure 14-4):
green battery charged
yellow Battery charging
red Battery discharging

You can abort the maintenance program at any time by switching the defibrillator on with the energy selector. In this case, however, the battery charge level is unknown.
For discharged batteries, the maintenance program may take up to 20 hours to complete.
At the end of the maintenance program, you can check the event memory for details of the battery maintenance routine.

15 Test Discharge

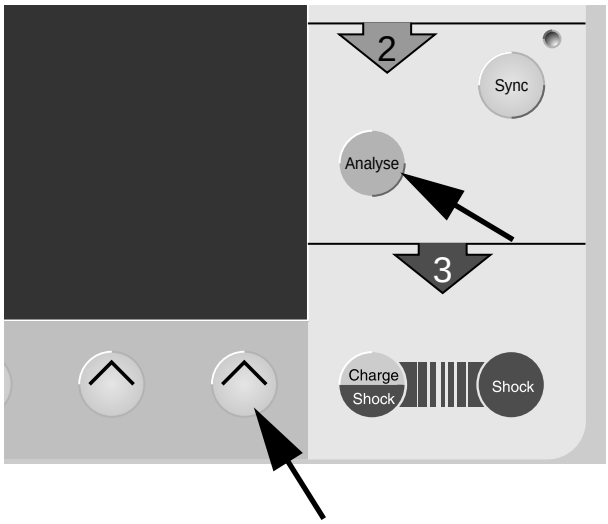


Figure 15-1. Buttons to activate the manual mode

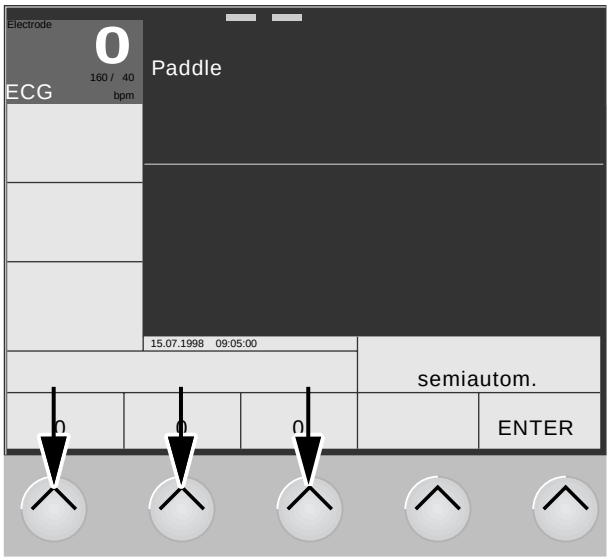


Figure 15-2. Buttons for entry of the password

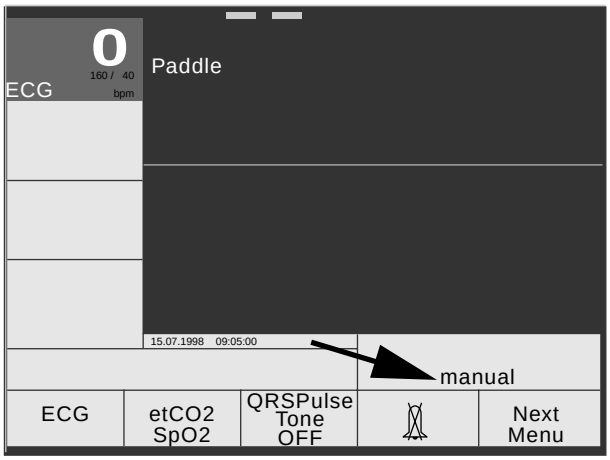


Figure 15-3. Defibrillator set up for manual operation

On defibrillators set up for semiautomatic defibrillation, a test discharge can be delivered only

– when you activate the manual mode (next section) or

– use a simulator.

How to toggle the defibrillator from semiautomatic to manual operation

- Simultaneously press **F5** and Analyse (Figure 15-1).

When the defibrillator is set up for "Semiautom./Button", it will immediately activate the manual mode.
When the defibrillator is set up for "Semiautom./Password", the screen for entry of the password appears (Figure 15-2).

- Enter the password (3-digit number) with ***F1, F2, F3.*** The factory-set password is 111 (also refer to chapter 13, section "Password").

When switched on again, the defibrillator will reactivate the operating mode selected in the setup menu.
Date and time of the change of operating modes is stored in the event memory.

When the defibrillator is set to "Semiautomatic", it cannot be switched to the manual mode. You will have to select another operating mode first from the setup menu (chapter 13 "Defibrillator Setup").

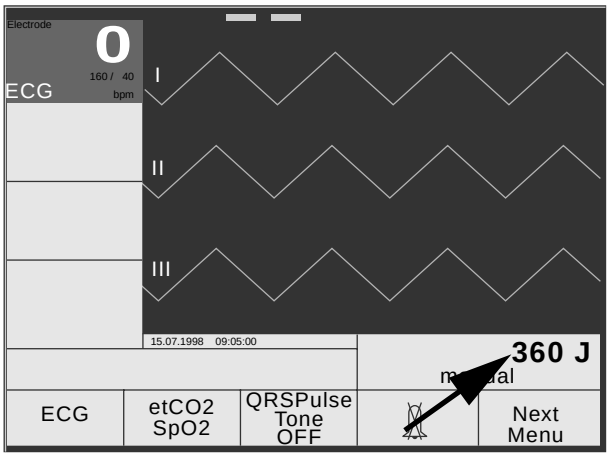


Figure 15-4. Indication of selected energy

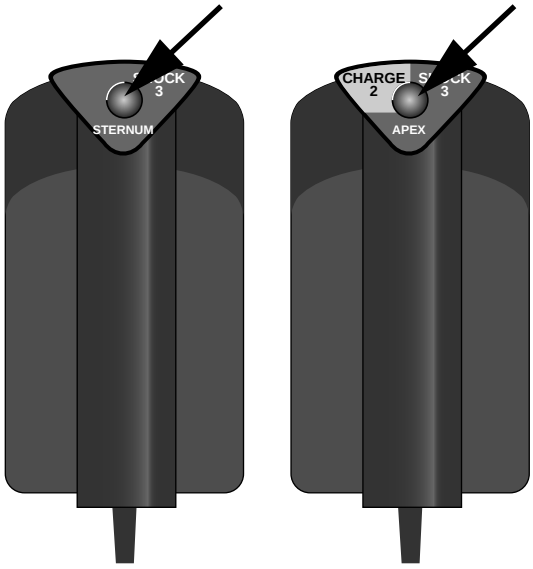


Figure 15-5. Buttons to initiate defibrillator charging and to trigger the shock

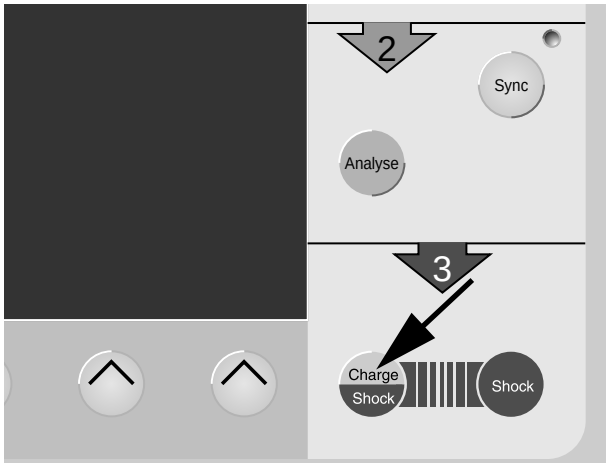


Figure 15-6. Button to initiate defibrillator charging when adhesive or internal electrodes are connected

Test Discharge (manual mode)

The correct release of the defibrillation shock can be checked by means of a test discharge. For this test, the stored energy is discharged into the device via two contacts in the paddle compartments. When adhesive pads are connected to the defibrillator, the test discharge is only possible with a suitable simulator; a test discharge with internal spoons is not possible.

- Set the energy selector to 360 J.

The selected energy will be displayed (Figure 15-4).

- Initiate defibrillator charging by pressing the ***Charge/Shock*** button on the right paddle (Figure 15-5), or by pressing Charge Shock on the control panel (Figure 15-6) when using adhesive pads.

When the selected energy is charged,
– the device emits an audio signal
– the color of the energy field changes to yellow
– the message "Energy available" appears.

Warning

Shock Hazard — When delivering the test discharge, hold on to the paddle handles and be careful not to touch the contact surfaces.

Do not touch the simulator while the shock is delivered. Do not place the simulator on a metal surface.

Test Discharge (semiautomatic defibrillator)

A special simulator is required to test the defibrillator performance in the semiautomatic mode.

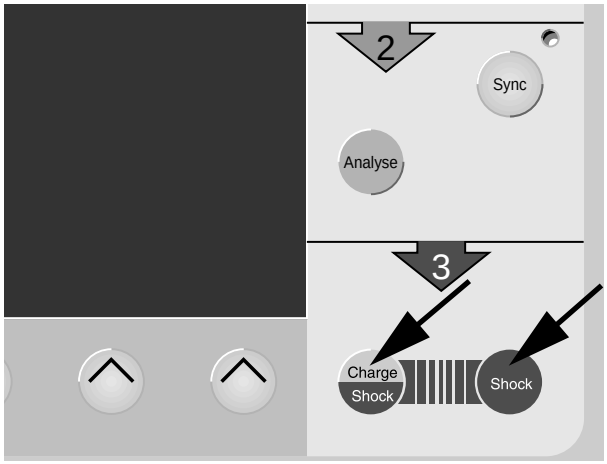


Figure 15-7. Buttons to deliver the shock

Caution

Equipment Damage — Do not trigger more than 3 consecutive test discharges (or internal safety discharges) with the maximum energy of 360 J with 15 minutes. Otherwise the device may reach inadmissible high temperatures.

Note

If the shock is not delivered within 30 seconds of charging, an internal safety discharge will be initiated.

- Now trigger the shock within 30 seconds. To do so, simultaneously press the two buttons on the paddles (or Charge Shock and Shock on the control panel, when using adhesive pads) (Figure 15-7).

After the shock release, the audio signal stops and the delivered energy is displayed for about 6 seconds. According to the requirements of the IEC / AAMI standards, this value must be between 306 and 414 Joules. At the same time, the defibrillator prints a 14-second ECG strip (incl. history of 4 seconds), if this function is enabled.

If the discharge circuit is interrupted (electrodes not properly inserted in their compartments, cable defect), a safety discharge will be initiated 200 ms after release of the test discharge.

- Switch off the Marquette Responder® 3000 (energy selector to "Off").

Incorrect Shock Delivery, Error Messages

If the energy of the test discharge is not within the specified limits, a defibrillation is possible all the same (it is the user's decision whether or not to employ the defibrillator). However, the device must be immediately checked and repaired by a service technician.

16 Operation in the Vehicle Mounting Unit, Mounting the AC Power Adapter

Operating the Defibrillator in the Vehicle Mounting Unit

When you place the defibrillator in the mounting unit, it will be powered from the ambulance power system. Check that the power supply contacts on the defibrillator and on the mounting unit (Figure 16-1) are clean. Always secure the defibrillator with **both** locking devices (Figure 16-1, arrows at top).

In the vehicle mounting unit, the defibrillator display is upside down. Therefore you can flip the display (see chapter 3, section "Display Flip").

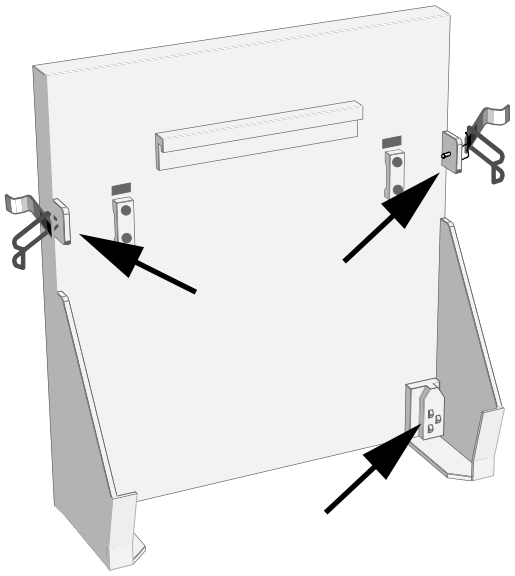


Figure 16-1. Vehicle mounting unit

Mounting the AC Power Adapter

The AC power adapter is screwed to the rear of the Marquette Responder® 3000.

- Remove the two legs (**a**, Figure 16-2) and the screws (**b**) on the underside.
- Attach the AC power adapter and secure it with the new screws supplied.
- Connect the device to the power line.
- Check that the batteries are charging.
- Remove the batteries and check the device performance (chapter 3 "Putting the Defibrillator Into Operation").

Note

On line power, the defibrillator charges to 360 Joules in approx. 9 seconds.

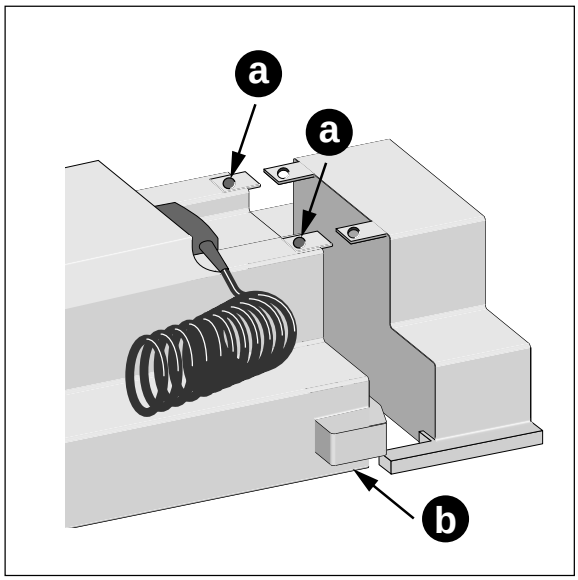


Figure 16-2. Mounting the AC power adapter

17 Error and System Messages

Message	**Effect**	**Explanation**	**Remedy**
D-RAM Error	device defect, device cannot be used		notify service
S-RAM Error	device defect, device cannot be used		notify service
FLASH Error	device defect, device cannot be used		notify service
EEPROM Error	restricted use for emergencies only, defibrillation possible	defective user setup (e.g. user setup cannot be saved)	press one of the function keys, notify service
Charge Energy Error	charged energy differs from selected energy, use device only in emergencies	error occurred last time the device was used (before switched off) and was saved	press one of the function keys, trigger test discharge, switch device off and on again; if error message recurs, notify service
Time Base Error	restricted use for emergencies only, defibrillation possible	all time-related data (e.g heart rate) may be erroneous	press one of the function keys, adjust time; if error message recurs, notify service
Battery		battery almost depleted	charge battery
HR, etC		alarm, violation of alarm limit	
Electrode		high ECG or defibrillation electrode impedance	reapply electrode
Check selector		energy selector is not indexing properly; defibrillation possible	set energy selector to the exact position; if error message recurs, notify service
Energy high		internal spoons are connected and selected energy is above 50 J; charged energy higher than selected energy; defibrillation possible	select a lower value (internal spoons) or trigger test discharge; if message recurs, notify service
Energy low		charged energy below selected energy; defibrillation possible (e.g. battery depleted)	trigger test discharge; if message recurs, notify service check battery
Device Behavior		**Explanation**	**Remedy**
Device not functioning properly		software problem	switch device off and on again; notify service

18 Cleaning, Maintenance

Cleaning, Disinfection and Sterilization

Electrodes, Device

Danger

- ***Shock Hazard — Before cleaning the device, disconnect it from the power line. Ensure that it is switched off and that it is not switched on while being cleaned. Danger to life! As a safety precaution, remove the batteries and disconnect the defibrillation electrodes from the defibrillator.***
- ***Shock Hazard, Equipment Damage — Liquids must not be allowed to penetrate the device. Devices into which liquids have entered must be immediately cleaned and checked by a service technician, before they can be reused.***

- Discard all disposable items immediately after use to prevent that they are reused.
- The paddles and their leads can be cleaned and disinfected by wiping them down with a gaze pad moistened with a cleaning solution or disinfectant. Before using the paddles again, however, make sure that they are completely dry.
- The device surface too can be wiped down with a cloth moistened with a cleaning solution or disinfectant. Liquids must not be allowed to enter the device.

Any cleaning agents and disinfectants commonly used in hospitals are suitable for cleaning of the device.

Caution

- ***Electrode Damage — Do not sterilize the electrodes for internal defibrillation (spoons) with hot air.***
- ***Cable Damage — Disconnect the cable from the electrodes before sterilization (arrow, Figure 18-2).***

- The internal electrodes are cleaned in the same way. The electrodes and connecting cables should be sterilized by the low-temperature plasma sterilization method. Alternative methods are ETO sterilization, water vapor (134 °C) or ionizing radiation. Ensure that internal defibrillation electrodes are sterilized before each use.

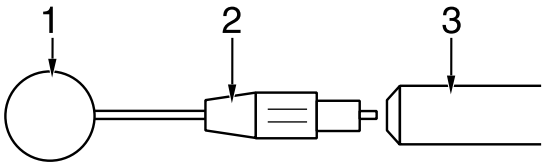


Figure 18-1. Inserting the spoon electrodes

Note

Having loosened the counter nut 2, you can easily alter the position of the contact paddle.

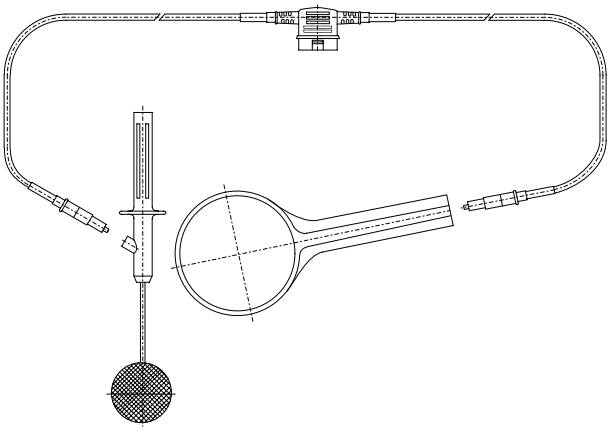


Figure 18-2. Counter electrode for internal defibrillation

Inserting the Spoon Electrode

- Screw the counter nut **2** (Figure 18-1) onto the electrode as far as it will go.
- Screw the contact paddle **1** into the handle as far as it will go, then bring it into the appropriate position.
- Now fix the contact paddle by screwing the counter nut **2** tight against the handle **3**.

External Counter Electrode for Internal Defibrillation

- Disconnect the electrode from its lead before cleaning or sterilizing it (Figure 18-2).
- Clean the electrode by rubbing it down with a cloth moistened with soap water. Use a disinfectant for disinfection. Do not immerse the electrode in the liquid.
- Low-temperature plasma sterilization is the recommended sterilization method. Alternative methods are ETO sterilization or ionizing radiation. (Please note: Frequent ETO sterilization reduces the life expectancy of the plastic material!) Do **not** autoclave the electrodes.

Maintenance

Checks before each use

- Before each use, visually inspect the device, the leads and electrodes for signs of mechanical damage.
- Also check the device performance as outlined in chapter 3 "Putting the Device Into Operation", and trigger a test discharge (chapter 15).

If you detect damages or impaired functions which may result in a hazard to the patient or the operator, the device must be repaired before it can be used again.

Checks at regular intervals

The Marquette Responder® 3000 is an emergency device and must always be ready for use. These checks must be carried out once a month:

- visual inspection of the device and the accessories
- performance check as outlined in chapter 3 "Putting the Device Into Operation"

Technical Inspections

For safety, the devices require regular maintenance. To ensure functional and operational safety of the Marquette Responder® 3000, Technical Inspections should be carried out on an annual basis.

These checks should be performed by persons with adequate training and experience.

The checks can be carried out by Marquette Hellige within the framework of a service contract.

The nature and scope of these checks are explained in the corresponding sections of the Service Manual.

Battery Replacement

NiCd batteries have a limited service life as their storage capacity deteriorates with age. For this reason, the batteries must be replaced every 3 years.

The device does not require any other maintenance.

Disposal at the End of Its Service Life

Note

At the end of their service life, the device described in this manual and its accessories must be disposed of in compliance with the applicable local waste control regulations. If you have questions regarding the disposal of the product or of the accessories, please contact Marquette Hellige GmbH or its representatives.

19 Technical Specifications

Operating Modes

– non-synchronized (defibrillation on demand)

– synchronized (cardioversion)

– semiautomatic (in the presence of shockable arrhythmias)

Energy Selection

by means of energy selector, energy to be delivered into 50 Ohms is indicated as a numerical value:

- energy adjustable in steps, energy values as energy delivered into 50 Ohms (internal defibrillation: energy limited to 50 Joules)

AutoSeq
2
5
7
10
20
30
50
100
150
200
300
360 Joules

- possible deviation from selected energy less than permitted by IEC

Defibrillator Charging

with capacitor; capacitor is charged from built-in battery, from 12-V DC power via vehicle power system or from the power line with optional AC power adapter buzzer indicating "charge done"

- capacitor charging time for energy setting of 360 J:
  - on line power and when inserted in vehicle mounting unit typically 9 s
  - with fully charged battery typically 6 s,
  - with partially discharged battery typically 7 s (max. 10 s)

Defibrillation Shock

capacitor discharge via induction coil (Lown / Edmark); exponential pulse shape, monophase, damped sinusoidal halfwave:

- pulse duration for an external resistance of 50 ohms approx. 4 ms, measured from the beginning of the pulse to the intersection of the zero line and the inflection point of the trailing pulse edge, according to AAMI DF-2
- in synchronized mode, the defibrillation shock is released within 40 ms of the R-wave trigger

Discharge Circuit

serial oscillating circuit in series with external resistance (patient):

- capacitance 34 µF
- inductance 26 mH
- equivalent resistance 6 ohms

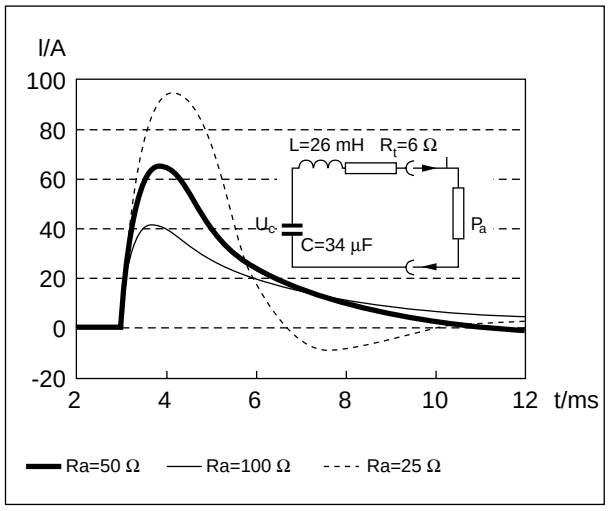


Figure 19-1. Current discharge curve (360 J)

Pulse Output

isolated, no conductive connection with enclosure, open-circuit and short-circuit-proof as required by AAMI DF-2:

- insulation test voltage 8 kV DC, type CF according to IEC 60601-2-4

Safety Discharge

capacitor discharge via internal load resistance:

- when the defibrillation shock is not triggered within 30 s of charging
- when the defibrillation shock is triggered, but the discharge circuit is interrupted, after 0.2 s
- when the selected energy is not reached, after 32 s
- in the presence of technical malfunctions
- when the energy selector is set to or "Off" after charging was initiated
- when a shock is delivered into open air,
- when the battery voltage is insufficient,

Test Features

- indicator for battery charging
- defibrillator test by discharging the stored energy into the integrated 50-ohm load resistance (max. twice within 15 minutes)
- 3-digit display of the delivered energy
- warning on LCD when discharge circuit is interrupted (e.g. defibrillation electrode not applied)
- automatic power-on self-test with error message

Synchronization

with ECG signal of either polarity:

- minimum ECG amplitude for reliable triggering approx. 0.50 mV and QRS width of 80 ms
- indicated by yellow LED
- SYNC marker on display

ECG Signal Input Via Defibrillation Electrodes

automatic switching to defibrillation electrodes when there is no patient cable or lead is open; differential input, isolated, IEC class CF, with overvoltage protection:

- input voltage range ± 10 mV
- input impedance > 1 MOhms
- differential DC voltage tolerance ± 1 V
- frequency response 1.2 Hz to 35 Hz (-3 dB)
- common-mode rejection > 80 dB
- patient leakage current: in normal condition < 10 µA, in single-fault condition < 100 µA
- detection of pacing pulses
  - pulse duration d_p > approx. 0.1 ms < 2.0 ms
  - pace marker independent of polarity
  - pulse amplitude a_p ± 10 to ± 700 mV
  - reverse current pulse a_0 ± 1 mV
  - time constant t_0 = 25 to 100 ms

ECG Signal Input Via Patient Cable

automatic switching to ECG electrodes, if they are applied;
differential input, symmetrically referred to N, isolated, IEC class CF;
7 standard leads via lead selector; input overvoltage protected (defibrillation-proof):

- input voltage range ±10 mV for recorder and display
- input impedance > 10 MOhms for 10 Hz
- common-mode dynamic range ±1 V
- differential DC voltage tolerance ± 0.6 V
- common-mode rejection (CMRR) RL referred to N > 65 dB, N referred to chassis > 110 dB
- band width 0.15 to 100 Hz,
  with 12 SL 0.08 to 100 Hz
- patient leakage current: in normal condition < 10 µA, in single-fault condition < 50 µA
- ground leakage currents: in normal condition < 0.5 µA, in single-fault condition < 1 µA
- voltage resistance referred to ground reference 3 kV (static)
- detection of pacing pulses
  - pulse duration d_p > approx. 0.1 ms < 2.0 ms
  - pace marker independent of polarity
  - pulse amplitude a_p ± 10 to ± 700 mV
  - reverse current pulse a_0 ± 1 mV
  - time constant t_0 = 25 to 100 ms
  - overall error < 20 % (typical)

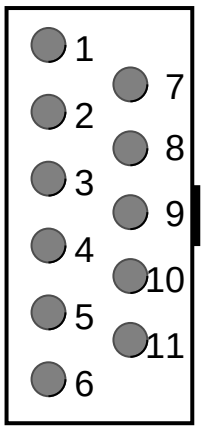
Signal Transmission

signal input --> amplification --> signal sampling --> AD conversion --> digital processing --> display and recorder

- adjustable gain: 0.5 – 1 – 2 cm/mV (with max. gain a 1-mV input signal results in 2 cm/mV)
- amplitude limited to the area of the waveform window on the display and to the recorder writing width
- signal sampling rate of 1000 Hz (reduction to 400 Hz)

ECG Signal Output ("Option" port)

- ECG lead shown in channel 1 on the display
- 1 V output signal for 1 mV input signal
- U_{max} ±2 V
- overall error < 3% (typical)
- R_L 500 Ω min.
- delay < 150 ms (not suitable for triggering of external devices)
- no electric isolation



9 = ECG
10 = chassis

Only connect devices that meet the requirements of EN 60601-1 and EN 60601-1-1, respectively.

Signal Display

active backlit VGA color LCD, 3-channel erase bar display, alphanumeric indication of alarms, gain, lead, QRS indicator, alarm limits, heart rate, energy and function key labels
At a gain of 1 cm/mV a 1-mV signal is 1 cm in size on the display.

- erase bar sweep speed 25 mm/s
- trace length in real-time mode 4.08 s
- SYNC marker
- display size: width 130 mm, height 97 mm
- VGA resolution 640 x 480 pixels (pitch 0.204 x 0.202 mm)
- displayed image can be reversed (180°)
- AC line filter 50/60 Hz
- muscle filter ECG 35 Hz, paddles 20 Hz

Systole Check

- heart symbol on display
- QRS beep (can be switched off)

Heart-Rate Measurement

derivation of trigger pulses from the ECG of either polarity, adaptive trigger threshold, calculation of the average rate, storage of the result, 3-digit display on LCD, alarm limits to the left of the HR

- measuring range 15 to 300 bpm
- digit height of HR reading 7.5 mm
- digit height of alarm limits approx. 2.0 mm
- minimum amplitude for reliable triggering >0,3 mV for an ECG signal with a QRS duration of 80 ms
- QRS trigger according to AAMI EC 13
- T-wave suppression up to 1 mV
- response time to HR changes approx. 5 s

Alarm System

electronic release of alarm

- when the heart rate violates one of the set alarm limits (after condition exists for 10 seconds): audio signal sounds (can be disabled), message "HR Alarm", alarm recording is initiated (configurable)
- when at least one of the selected electrodes is off the patient: audio signal sounds (only when patient cable is connected), message "Alarm, Electrode" on display
- adjustment range for ECG alarm limits: off, 15 to 300 bpm (not overlapping)
- adjustment range for $etCO_2$ alarm limits: off, 5 to 76 mmHg
- digit height of the displayed alarm limits 2.0 mm

Recording

manually initiated continuous ECG recording, or recording of the delayed ECG signal from memory (14 seconds, incl. history of 4 seconds) upon alarm and

alphanumeric annotation of the following parameters in the paper margin:

- Heart rate
- ECG lead
- filter(s)
- date, time
- paper speed
- reason for recorder start (shock, alarm, manual, event, auto, 12SL, test, recall, trend, text)
- selected energy [J into 50 Ohms]
- delivered energy
- SYNC marker
- user/hospital/practice name

After recording the ECG, the recorder will print an intervention report (name, date of birth, user, comments – entered by the user - defibrillation mode, selected and delivered energy, number of shocks and alarm limits).

Direct writing with rectangular coordinates using thermorecording technology (printhead with electronically controlled thermal elements records on thermosensitive paper), roll paper, paper transport by stepper motor:

- number of recorder channels: 3
- paper width: 90 mm
- max. roll diameter 55 mm (roll with 40 m of HELLIGE CONTRAST® paper)
- printhead resolution: vertically 8 dots/mm, horizontally 40 dots/mm at 25 mm/s
- recorder speed 25 mm/s ±5 %
- end-of-paper detection and message on display

To prevent damage to the printhead use only the original HELLIGE CONTRAST paper.

Memory

- storage of 180 minutes of ECG data with full intervention report
- storage of three 12SL ECG analysis reports including the ECG
- 1 and 4-hour trends for ECG and $etCO_2$
- storage of the most recent 250 actions (e.g. device on/off, alarms, defibrillation energy) including date and time

Pacemaker

- Operating Modes: Demand, Fix
- pacer rate: 30 to 200 P/min +-5%
- pacer current: 0 to 200 mA +- 10% (for 500 Ω)
- pulse width: 20 ms
- pulse shape: monophase square wave pulse

SpO_2

- saturation: 0 to 100% in increments of 1 %
- rate: 0 to 250 P/min in increments of 1 P/min
- limit value: OFF, 60 to 100%
- display of the plethysmogram
- C-Lock ECG synchronization
- Integration time: 4, 8, and 12 seconds
- measurement error: 70 to 100% ±2 digits
50 to 69% ±3 digits
- pulse readout 1.2% or ±1 P/min

$etCO_2$

semi-quantitative measuring method, using IR technology

This method is based on the condition that the inspired air is free of CO_2.

- measuring range: 0 to 76 mmHg
- error (at ambient pressure of 1 atmosphere and no CO_2 in the inspired air: ± 4 mmHg (≤40 mmHg); ± 10% (>40 mmHg)
- response time: approx. 200 milliseconds
- rise time: approx. 100 ms (10 to 90%)
- warm-up time : approx. 10 seconds
- dimensions: 58H × 39W × 17D mm (w/o. airway adapter, cable and CO_2 sensor)
- weight: 100 g (incl. CO_2 sensor)
- safety standard IEC 60601-1, type BF
- capnogram display

Power supply

Battery

power supply from 1 or 2 exchangeable NiCd batteries

- rated voltage 12 V
- rated capacity 2.0 Ah
- battery charging in device
- max. charge time of a depleted battery 4 hours
- operating time with one fully charged battery approx. 60 shocks of 360 Joules each (into 50 Ohms) or 1.4 hours of monitoring (1 h if pacemaker, $etCO_2$ and SpO_2 measuring system are used)

Line Power (optional)

- 100 V to 240 V ± 10 % (47 Hz to 63 Hz)
- power consumption at 230 V:
  - during defibrillator charging 240 VA
  - during monitor operation 40 VA
  - during battery charging 25 VA
- max. charge time of a depleted battery 4 hours
- intrahospital use (IPX 1)

Operation in Vehicle Mounting Unit, Power from 12 V DC Ambulance Supply System:

- 11.5 to 18 V
- power consumption
  - during defibrillator charging 130 W
  - during monitor operation 27 W
  - during battery charging 14 W

Operational readiness

- 4 seconds, incl. automatic self-test

Operating position

any, horizontal with AC power adapter

Type of Protection

protected against splashing water; Marquette Responder: IPX 4 (batteries inserted, cables connected)
AC power adapter: IPX 1

Environment

Operation

operation under the following conditions considered to be normal:

- temperature between 0 and +45 °C
- relative humidity between 5 % and 95 %, no condensation
- atmospheric pressure between 700 and 1060 hPa
- vibration acc. to MIL 810E Cat.10 and prEN 1789

Transport and storage

- temperature between -25 and +70 °C
- relative humidity between 10 % and 95 %, no condensation
- atmospheric pressure between 500 and 1060 hPa (with $etCO_2$ adapter cable: 700 and 1060 hPa)

Dimensions

- width 307 mm
- height 202 mm
- depth 412 mm (without AC power adapter)
  476 mm (with AC power adapter)

Weight

- with one battery approx. 8 kg (w/o. AC power adapter)

20 Order Information

Subject to change. Always refer to latest list of accessories.

101 164 01	Marquette Responder® 3000**,** basic system, manual operation, recorder
101 264 02	Marquette Responder® 3000**,** basic system, manual operation, pacemaker, recorder
101 264 03	Marquette Responder® 3000**,** basic system, manual operation, pacemaker, SpO_2, recorder
101 164 13	Marquette Responder® 3000**,** basic system, manual operation, SpO_2, recorder
101 164 14	Marquette Responder® 3000**,** basic system, semiautomatic operation (convertible to manual operation), SpO_2, recorder
101 164 04	Marquette Responder® 3000**,** basic system, semiautomatic operation (convertible to manual operation), recorder
101 264 05	Marquette Responder® 3000**,** basic system, semiautomatic operation (convertible to manual operation), pacemaker, recorder
101 264 06	Marquette Responder® 3000**,** basic system, semiautomatic operation (convertible to manual operation), pacemaker, SpO_2, recorder

Options

205 108 01	AC power adapter
384 018 86	Upgrade kit, semiautomatic
384 018 90	Upgrade kit, 12SL

Accessories
ECG

412931-002	Patient trunk cable, 5-lead cable, 3.6 m, IEC, MultiLink
412931-001	Patient trunk cable, 5-lead cable, 3.6 m, AHA, MultiLink
416035-002	Patient trunk cable, 10-lead cable, 3.6 m, IEC, MultiLink
416035-001	Patient trunk cable, 10-lead cable, 3.6 m, AHA, MultiLink
384 018 10	Set of 5 leadwires, 70 cm, clip connector, IEC, MultiLink
384 018 11	Set of 5 leadwires, 70 cm, clip connector, AHA, MultiLink
414556-003	Set of 5 leadwires, 74 cm, clip connector, for limb leads and C1, IEC, MultiLink
414556-001	Set of 5 leadwires, 74 cm, clip connector, for limb leads and V1, AHA, MultiLink
416467-004	Set of 5 leadwires, 74 cm, clip connector, for C2 to C6, IEC, MultiLink
416467-003	Set of 5 leadwires, 74 cm, clip connector, for V2 to V6, AHA, MultiLink
919 200 31	Disposable adhesive electrode for adults, press stud, silver-silver chloride, pregelled, diam. of contact surface 20 mm, 200/cs.
217 320 01	Adhesive electrode for children, silver-silver chloride, press stud, reusable
217 321 01	Adhesive electrode for adults, silver-silver chloride, press stud, reusable

Consumables

226 168 02	Chart paper, 90 mm, 10 rolls
217 123 01	Adhesive rings for electrode 217 320 01, 500/cs.
927 223 00	Adhesive rings for electrode 217 321 01, 500/cs.
217 083 05	Electrode cream, pkg. of 10 tubes, 100 ml per tube
217 083 18	Electrode cream, 250-ml bottle, refillable
217 083 14	Electrode cream, 5-l container
930 115 82	Dispenser, 30 ml

External defibrillation

217 333 01	Two paddles for external defibrillation with shock buttons (d)
217 333 02	Two paddles for external defibrillation with shock buttons (e)
217 329 01	Defibrillation electrode anterior - posterior
919 202 94	Disposable defibrillation pad, rectangular, for adults (1 pair)
919 202 95	Disposable defibrillation pad, rectangular, for children (1 pair)
223 383 01	Connecting cable for defibrillation electrodes 919 202 94/95

Internal defibrillation

217 308 01	Pair of defib electrodes for internal defibrillation (w/o. contact insert)
384 013 19	Contact inserts (2), internal, for adults
384 013 20	Contact inserts (2), internal, for children
384 013 21	Contact inserts (2), internal, for babies
919 202 36	External counter electrode for internal defibrillation

$etCO_2$

220 106 01	$etCO_2$ sensor
711 053 01	$etCO_2$ airway adapter (25/cs.)

SpO_2

223 394 01	Connection cable for the following probes (length: 4 m)
701 240 21	Standard finger probe for adults > 40 kg, reusable, type DS-100-A
407705-005	Disposable nose probe for adults > 50 kg, flexible, type R-15, 12/cs.
701 240 22	Disposable probe for children and adults (10 to 50 kg), flexible, type D-20, 24/cs.
701 240 26	Disposable probe for children (1 to 20 kg), flexible, type I-20, 24/cs.
701 240 27	Disposable probe for adults > 30 kg, flexible, type D-25, 24/cs.
701 240 32	Disposable probe for neonates < 3 kg and for adults > 50 kg, 24/cs.

Pacemaker

919 202 94	Disposable defibrillation pad, rectangular, for adults (1 pair)
919 202 95	Disposable defibrillation pad, rectangular, for children (1 pair)
223 383 01	Connecting cable for defibrillation electrodes 919 202 94/95

Miscellaneous

227 490 02	Operator's Manual
931 099 56	Carrying bag, no labeling
919 062 00	Power cord, EURO
919 201 81	Power cord, US
919 203 37	Power cord, UK
401855-107	Power cord, CH
303 446 31	Rechargeable battery, 2 Ah
701 279 01	Battery Station ASU 3000
202 317 01	Vehicle mounting unit with 12 V DC power supply
202 317 02	Vehicle mounting unit with 12 V DC power supply, US version
223 425 01	Adapter cable, 12 V
919 200 37	Potential equalization cable, 3 m
200 172-001	Field Service Manual
202 317 03	Wall-mount system with AC power adapter

Appendix

The Arrhythmia Detection Program

Overview

The arrhythmia detection program used in the Marquette Responder® Series defibrillators was developed by Marquette Medical Systems, Inc. After initial performance evaluation in the laboratory,(against recognised databases .i.e. MIT* and AHA**), independent clinical evaluation was performed in hospital and field settings. The hospital tests were performed in over 500 witnessed cardiac arrests and the program performance was very successful. Pre-hospital evaluation followed and the arrhythmia detection program was found to perform equally well. Moreover, the algorithm was tested against the Marquette Hellige database with over 150 true prehospital ECG rhythms.

Arrhythmia Detection

The "accuracy" of any arrhythmia program is quantified in terms of;

- Sensitivity: in this case, the ability to identify correctly a shockable rhythm
- Specificity: the ability to correctly identify non-shockable rhythms

An ideal system would have a sensitivity and specificity of both 100%, but in practice there is always a trade-off between the two.

The consensus opinion published by AAMI***(TIR #2-1987), is that specificity should be as high as possible, even at the sacrifice of some sensitivity. This approach minimizes the likelihood of shocking a non-shockable rhythm. However, this does mean that a system may not be able to identify **every** shockable rhythm.

The arrhythmia detection program of the Marquette Responder® 3000 achieves a sensitivity of 86 % and a specificity of 99.8 %. These values refer to ventricular fibrillation and ventricular tachycardia rhythms.

VT is shockable in the presence of a non-perfusing, high rate VT. There is no consensus as to what constitutes a "high rate". Therefore, in order to achieve a high specificity a rate of 120 bpm is used to identify shockable VT.

The algorithm uses a 'Majority Decision' approach to advising a shock, whereby two-of-three ECG analysis segments must be in agreement(each segment is 4 s).

The overall performance of the algorithm was tested in ambulance trials. It is important to bear in mind the many factors that can affect the performance of such a system. These include skin preparation, electrode quality and placement, as well as patient or vehicular motion.

* Massachusetts Institute of Technology
** American Heart Association
*** Association for the Advancement of Medical Instrumentation

marquette

A GE Medical Systems Company

EC Declaration of Conformity

Document No. 13-99

Marquette Hellige GmbH
Munzinger Strasse 3, D-79111 Freiburg, Germany

We herewith declare that the product

Defibrillator Responder 3000, product status **Version 2.0**
(including system components and accessories, UMDNS-Code: 17-116)

fulfills the requirements of the following directives, standards and normative documents:

1. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

2. EN 60601-1: 1990 + A1: 1993 + A2:1995 / IEC 60601-1: 1988 + A1: 1991 + A2: 1995
   EN 60601-1-1: 1993 + A1: 1996 / IEC 60601-1-1: 1992 + A1: 1995
   EN 60601-1-4: 1996 / IEC 60601-1-4:1996
   IEC 60601-2-4: 1983
   EN 60601-2-27: 1994 / IEC 60601-2-27: 1994
   prEN 1789: 1997
   PrEN 865:1996

3. EN 60601-1-2: 1993 / IEC 60601-1-2: 1993
   EN 55011: 1991 / CISPR 11: 1990, modified,
   device group 1, **class A**

Compliance of a representative sample of the designated product with the "essential requirements" of Annex I of the Directive 93/42/EEC has been certified by

Marquette Hellige GmbH, Quality Management and Certification, Munzinger Str. 3, D-79111 Freiburg, Germany, Test Report No. CE-H-013 of 31 March 1999.

The medical device has been assigned to class **IIb** as specified in Annex IX of the Directive 93/42/EEC. It bears the mark

CE-0366

The designated product has been designed, manufactured and tested under a quality management system according to EN ISO 9001, EN 46001 and Annex II Section 3.2 of Directive 93/42/EEC concerning medical devices. The conformity of the quality management system has been certified by:

VDE Testing and Certification Institute

Date 19.1.2000

Hubert Renck
Director Engineering
The technical documentation filed in the RA/QA Dept.

Index

1

12SL ECG analysis program 46

A

AC line filter 43
AC power adapter, mounting 73
Accessories 84
Adhesive electrode, defibrillation, pacing 8
Airway adapter 54
Alarm limits, etCO2 56
Alarm limits, SpO2 53
Application Tips, SpO2 50
Arrhythmia detection program 31, 87
Arrhythmia monitoring 45, 64
Autosequencing 19

B

Battery charging 67
Battery maintenance program 69
Battery power operation 68
Battery power operation, charge level 68
Battery replacement 77
Biocompatibility 5

C

Capnogram 57
Cardioversion 26
Caution, definition 4
CE marking 4
Channel waveforms, assign 42
Charge level 68
Charging the batteries 67
Charging unit 67
Chart paper, load 62
Checks at regular intervals 77
Checks before each use 77
Cleaning recommendations 75
C-Lock ECG synchronization 50, 52
Color concept 5, 13
Contrast adjustment 14
Controls and indicators 6
Counter electrode for internal defibrillation 76
Current discharge curve 78

D

Danger, definition 4
Date format 64
Date, enter 64
Dead space volume 55
Defibrillating the patient in the semiautomatic mode 32
Defibrillation of children 21
Defibrillation pads, application 22
Demand mode 38
Disinfection 75
Display flip 14
Disposable defibrillation pads 22
Disposal of the device 77

E

ECG acquisition via separate ECG electrodes 35
ECG display 41
ECG memory 59
ECG signal size 42
Electrode for internal defibrillation 8
EMC requirements 11
Error messages 74
Event memory 58
Event texts 66
Events, primary 58
Expiration date, defib pads 22
Explosion hazard 9

F

Fixed-rate mode (pacemaker) 40
Functional description 5

G

Gain selection 42
General information 4

H

Hardcopy 61
Heart rate monitoring 41, 44
Hemoglobin saturated with oxygen 49

I

Indicators 6
Infrared spectroscopy 54
Integration time 52
Intended use 5
Interpretation program 48
Intracardiac application 9

L

Language selection 65
Literature 11, 31, 49
Low-temperature plasma sterilization 75

M

Maintenance 77
Manual defibrillation, switchover from semiautomatic 17, 70
Measurement and interpretation program 41
Measurement program 48
Memories of the defibrillator 58
Memories, clear 60
Monitoring the heart rate 44
Multiple portable socket outlets 10
Muscle filter 43

N

Non-synchronized defibrillation 19

O

Options 66
Order information 84

P

Pacemaker 36
Pacemaker patients 45
Pacemaker, guidelines for application 37
Pacemaker, turn off 39
Packaging material, disposal 11
Paddle application 19
Paddles 8
Part numbers 84
Password, change 65
Password, enter 65
Performance check 16
Plethysmogram 53
Power supply 5
Primary events 58
Probes (SpO2) 49
Pulse oximetry 49

R

Recording 61
Revision code 3
Revision history 3
Rotate display 14

S

Safety information, etCO2 55
Sawtooth signal 13
Selecting the HR source 53
Semiautomatic defibrillation 30, 31
Setup 14
Setup menu 63
Shock counter 21
Specifications 78
SpO2 measurement 49
SpO_2 measurement, begin 52
Spoon electrode, insertion 24, 76
Sterilization 75
Switching from semiautomatic to manual defibrillation 17, 70
Symbols used on the device, explanation 7
Synchronization pulses 38
Synchronized defibrillation 26

T

Technical inspections 77
Technical Specifications 78
Test discharge 71
Therapy, end 21
Tidal volume 55
Time, enter 64
Transcutaneous pacemaker 36
Transport conditions 11
Trend memory 60
Trigger signal for cardioversion 26

V

Vehicle mounting unit 67, 73

W

Warning, definition 4
Warranty 4